PATIENT CONCERNS INVENTORY HEAD & NECK AS AN INDIVIDUALISED APPROACH TO ASSESS POST-TREATMENT OUTCOMES AMONG ORAL CANCER PATIENTS IN MALAYSIA

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DEPARTMENT OF COMMUNITY ORAL HEALTH
AND CLINICAL PREVENTIVE FACULTY OF DENTISTRY
UNIVERSITY OF MALAYA
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THESIS SUBMITTED IN FULFILMENT OF THE REQUIREMENTS FOR THE DEGREE OF DOCTOR OF DENTAL PUBLIC HEALTH

DEPARTMENT OF COMMUNITY ORAL HEALTH
AND CLINICAL PREVENTIVE FACULTY OF DENTISTRY
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ABSTRACT

Background: Oral cancer and its treatment undisputedly impacts patients‘ quality of life, posing a challenge to clinicians in managing them optimally. Identifying patients‘ concerns is central to holistic patient care; as such time constraints faced by clinicians during consultation sessions may pose a barrier in identifying such concerns effectively. The use of PCI-H&N during post-treatment oral cancer consultation sessions has previously shown to be beneficial, simultaneously promoting effective patient- clinician communication during consultations. **Objectives:** This study aimed to determine the feasibility of the PCI-H&N in assessing post- treatment oral cancer patients concerns and its relationship with patients‘ HRQoL, psychological distress and satisfaction during their follow-ups consultation. **Methods:** A mixed mode study design was conducted among post-treatment oral cancer patients in multiple centres of Oral Maxillofacial Surgery Clinics in Malaysia, in two phases; i) Phase I: 3-armed pragmatic RCT among post-treatment oral cancer patients, and ii) Phase II: focus group discussion among health personal. A sample of 123 post-treatment oral cancer patients attending their follow-up reviews were recruited comprising Malaysians aged 18 years and above, completed treatment and on follow-up from one month until five years or more. A set of self-administered questionnaires was administered pre and post-consultation. The primary outcomes were patients‘ HRQoL assessed by the FACT-H&Nv4.0, psychological distress by using Distress Thermometer and satisfaction with the follow-up consultation measured by a study specific questionnaire. The feasibility and preferred versions of PCI-H&N were secondary outcomes assessed with specific questionnaires respectively. The data were analysed descriptively; multiple linear regression and multivariate logistic regression analyses were used to determine possible predictors of patients‘ HRQoL and psychological distress. **Results:** Response rate was 88% with 63% patients completing the post-consultation questionnaires. The median

(IQR) number of the PCI-H&N items selected was three (1-5.5) and 43.5% patients selected four or more concerns. ‗Recurrence or fear of cancer coming back‘ (31.8%) was most frequently selected. A shorter time was taken by patients to complete the paper version (4.0 ± 3.7 mins; 95% CI: 3.87, 5.87) than the computerised web-based version (6.0 ± 4.5 mins; 95% CI: 5.55, 8.92). A high number of concerns was strongly significant among patients of ‗one-month to one-year post-treatment‘ (n=84%) (p=0.001). Significant association existed between ‗time after treatment completed‘ and concerns of ‗chewing/eating‘, ‗mouth opening‘, ‗swelling‘, ‗weight‘,‘ ability to perform‘, ‗cancer treatment‘ and ‗supplement/ diet-related‘. ‗Chewing/eating‘ scored highly for predicting low HRQoL (p< 0.0001) followed by ‗appearance‘ and ‗ability to perform recreation activities‘ (personal function domain). Patients at risk of psychological distress were 14 times more likely to select ‗ability to perform recreation activities‘ and 7 times more likely to select ‗feeling depressed‘. No significant association was identified between patients satisfaction with the consultation and patients concerns. **Conclusion:** The use of PCI-H&N as an individualised approach during follow-up consultations could potentially enhance patient-centred care by improving doctor-patient communication, identifying oral cancer patients' concerns and further improving quality care delivery for Malaysian oral cancer patients. In addition, the computerized web-based version is in tandem with patient health management system advancement.

Keywords: Patient Concerns Inventory (PCI), health-related quality of life, psychological distress, oral cancer and paper version.

ABSTRAK

Latar belakang: Tidak dinafikan bahawa kanser mulut dan rawatannya mempengaruhi kualiti hidup pesakit dan memberi cabaran kepada doktor dalam mengendalikan pesakit secara optimum. Penjagaan pesakit secara holistik adalah dengan mengenalpasti masalah pesakit, namun kekangan masa doktor menghadkan sesi perundingan dan menghalang dari mengenal pasti masalah tersebut secara berkesan. Penggunaan PCI-H&N semasa sesi perundingan telah terbukti bermanfaat serta menggalakkan komunikasi secara berkesan antara pesakit-doktor. **Objektif:** Kajian ini bertujuan menentukan kemampuan PCI-H&N dalam menilai kebimbangan pesakit kanser mulut pasca-rawatan dan hubungannya dengan HRQoL pesakit, tekanan psikologi dan tahap kepuasan semasa sesi konsultasi. **Kaedah:** Kajian secara mod campuran dilaksanakan di kalangan pesakit kanser mulut pasca-rawatan di beberapa Klinik Bedah Mulut dan Maksilofasial di Malaysia. Dijalankan dalam dua fasa i) Fasa 1: 3-bahagian RCT pragmatik di kalangan pesakit kanser mulut pasca-rawatan, dan ii) Fasa 2: perbincangan fokus secara berkumpulan di kalangan kakitangan kesihatan. Seramai 123 orang pesakit kanser mulut pasca-rawatan yang menghadiri lawatan susulan telah mengambil bahagian. Kelayakan adalah warganegara Malaysia berumur 18 tahun dan ke atas, telah selesai rawatan, dan mengikuti rawatan susulan dari tempoh satu bulan hingga lima tahun atau lebih. Satu set soal selidik yang dilapor sendiri diberikan kepada pesakit sebelum dan selepas sesi perundingan. Keberhasilan utama kajian adalah HRQoL pesakit diukur menggunakan *FACT-H&Nv*4.0, tekanan psikologi dengan menggunakan *Distress Thermometer* dan kepuasan pesakit dengan konsultasi diukur dengan borang soal selidik khusus kajian. Kebolehlaksanaan dan pilihan versi PCI-H&N adalah hasil sekunder yang dinilai dengan menggunakan soal selidik khusus kajian. Data dianalisa secara deskriptif; analisa regresi linear berganda dan analisa regresi logistik multivariat bagi meramalkan HRQoL dan tekanan psikologi pesakit.

Keputusan: Kadar respons pesakit adalah 88% dengan 63% pesakit telah melengkapkan soal selidik selepas perundingan. Median (IQR) bagi item PCI-H&N yang dipilih adalah tiga (1-5.5) dan 43.5% pesakit memilih empat atau lebih jenis kebimbangan. ‗Kejadiansemula atau ketakutan barah akan kembali‘ (31.8%) adalah paling kerap dipilih. Masa yang lebih singkat diambil oleh pesakit menggunakan versi kertas (4.0 + 3.7 minit; 95% CI: 3.87, 5.87) berbanding versi berasaskan web-berkomputer (6.0 + 4.5 minit; 95% CI: 5.55, 8.92). Bilangan kebimbangan yang tinggi adalah signifikan di kalangan pesakit ‗satu bulan hingga satu tahun selepas rawatan‘ (n = 84%) (p = 0.001). Hubungan adalah signifikan antara 'masa selepas rawatan selesai' dengan masalah 'mengunyah/makan', 'membuka mulut', 'bengkak', 'berat badan', 'kemampuan melakukan aktiviti', 'perihal rawatan kanser' dan 'makanan tambahan/berkaitan dengan diet'. ‗Mengunyah/makan‘ merupakan pilihan tertinggi bagi meramalkan HRQoL pesakit yang rendah (p <0.0001) diikuti dengan ‗penampilan‘ dan ‗kemampuan untuk melakukan aktiviti rekreasi‘ (domain fungsi peribadi). Pesakit berisiko mengalami tekanan psikologi adalah 14 kali lebih cenderung memilih ‗kemampuan untuk melakukan aktiviti rekreasi‘ dan 7 kali lebih cenderung memilih ‗merasa tertekan‘. Tiada hubungan yang signifikan antara kepuasan pesakit dengan konsultasi dengan masalah pesakit. **Kesimpulan:** Penggunaan PCI-H&N sebagai pendekatan individu semasa perundingan susulan berpotensi meningkatkan pengendalia pesakit secara berpusatkan dengan meningkatkan komunikasi doktor-pesakit, mengenal pasti kebimbangan pesakit kanser mulut dan meningkatkan lagi tahap kualiti penjagaan pesakit kanser di Malaysia. Selain itu, versi berasaskan web-berkomputer merupakan langkah yang seiring dengan kemajuan sistem pengurusan kesihatan pesakit secara berkomputer.

Kata kunci: Inventori Keprihatinan Pesakit (*PCI*), kualiti hidup yang berkaitan dengan kesihatan, tekanan psikologi, kanser mulut dan versi kertas.

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May Allah grant all of you good health and shower you with His blessing.

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LIST OF SYMBOLS AND ABBREVIATIONS

WHO	:	World Health Organization
GLOBOCAN	:	Global Cancer Observatory
ASEAN	:	Association of South Asian Nations
QoL	:	Quality of life
HRQoL	:	Health-related quality of life
NCCN	:	National Comprehensive Cancer Network
PROMs	:	Patient-reported outcome measures
QPL	:	Question prompt lists
MDT	:	Multiple disciplinary team
TST	:	Touch screen technology
COVID-19	:	Coronavirus disease 2019
PCI-H&N	:	Patient Concerns Inventory for Head and Neck
FACT-H&N	:	Functional Assessment of Cancer Therapy Scale
OMFS	:	Oral Maxillofacial Surgery
IARC	:	International Agency for Research on Cancer
ICD	:	International Classification of Disease
SEA	:	South-East Asian
SEARO	:	South-East Asia Region
DNA	:	Deoxyribonucleic acid
OSCC	:	Oral squamous cell carcinomas
OPMD	:	Oral potentially malignant disorders
HPV	:	Human papillomavirus
MDT	:	Multiple disciplinary teams
IOM	:	Institute of Medicine

PCC : Patient-centred care

FGD : Focus group discussion

MOH : Ministry of Health

PEG : per-endoscopic gastrostomy

TNM : Tumour, Node, Metastasis

SEER : Surveillance, Epidemiology and End Results

HADS : Hospital Anxiety and Depression Scale

DT : Distress Thermometer

DASS : Depression, Anxiety Stress Scale

BDI : Beck Depression Inventory

SCIP : Satisfaction with cancer information profile

DPC : Doctor-patient communication questionnaire

PPRI : Physician-patient relationship

CNQ-SF : Cancer Needs Questionnaire – Short Form

SCNS-SF 34 : Supportive Care Needs Survey – Short form 34

SUNS : Survivors Unmet Needs Survey

CPNS : Cancer Patient Need Survey

FRAME-IT : Feasibility, Reach-out, Acceptability, Maintenance, Efficacy, Implementation and Tailorability

RE-AIM : Reach, Efficacy, Adoption, Implementation and Maintenance

PRECIS : Pragmatic-explanatory continuum indicator summary

NDOP : New Dental Officer Programme

OCRCC : Oral Cancer Research & Coordinating Centre

MAQ : Malaysian-added questions

PWB : Physical well-being

SWB : Social well-being

EWB	:	Emotional well-being
FWB	:	Functional well-being
HNS	:	Head and neck subscale
VAS	:	Visual Analog Scale
FTKL	:	Federal Territory of Kuala Lumpur
NMRR	:	National Medical Research Register (NMRR)
IA-HOD	:	Investigator Agreement-Head of Department
ITT	:	Intention-to-treat
ID	:	Identification

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CHAPTER 1: INTRODUCTION

1.1 Study background

Non-communicable diseases is one of the public health challenges in the 21st century. According to WHO (2018), cancer is expected to be the leading cause of death for 1:6 deaths (WHO website: cancer key facts, 2018; Ilbawi & Velazquez-Berumen, 2018). Incidence of oral cancer (C00-C06) is estimated to be increasing yearly (GLOBOCAN 2018), estimated 354,864 new cases of lip and oral cavity cancers (2.0% of all sites) with 177,384 deaths (1.9% of all sites) worldwide in 2018 (Bray, Ferlay, Soerjomataram, Siegel, Torre & Jemal, 2018). In ASEAN countries, oral cancer was ranked as the fifth most common cancer and it contributes about 50% of all new cancer cases (Kimman, Norman, Jan, Kingston, & Woodward, 2012). In Malaysia (2012), oral cancer incidence was 3.0 ASR (age-standard rate) of 776 patients and it is estimated to rise with increases of up to 31.1% and increase of 32.8% of mortality (Cheong, Vatanasapt, Yi-Hsin, Zain, Kerr & Johnson, 2017).

1.2 Problem statement

The life-journey of oral cancer survivors is ridden with challenges before and after treatment. Although oral cancer is not among the global leading cancer compared to other cancers (example GLOBOCAN, 2018: lung, breast, prostate, colorectal, stomach and liver), the disfigurement and dysfunction caused by oral cancer and its treatment may affect the basic functions of daily life such as eating, swallowing, speech, pain, and problems with social functioning especially after surgery; thus, affecting patients‘ quality of life (QoL) and the people around them (Brown & Yabroff, 2006; Ghazali, Roe, Lowe, & Rogers, 2015; Stewart & Wild, 2014; Weymuller Jr et al., 2000). Oral cancer survivors often have to cope with long-term effects such as altered psychological distress levels and reduced quality of life in terms of their social, physical, economic, and spiritual aspects (Peach et al., 2018; Rathod, Livergant, Klein, Witterick, & Ringash, 2015). Additionally, oral cancer patients are subject to high treatment cost, possibility of permanent impairment and higher mortality rate (Reichart & Way, 2006). Post-treatment patients‘ satisfaction levels, often, are dependent on their improved sense of well-being and reduced psychological distress (Llewellyn, Horne, McGurk, & Weinman, 2006; Llewellyn, Weinman, McGurk, & Humphris, 2008). The impact varies individually according to the cancer stages, site of cancer, treatment related issues patients‘ age and social background (Rogers, El-Sheikha, & Lowe, 2009; Vartanian, Rogers, & Kowalski, 2017). Tongue is the commonest site for oral cancer and surgery is the mainstay of treatment (Balasundram, Mustafa, Ip, Adnan, & Supramaniam, 2012). Tongue resection may result in impairment of speech, mastication, swallowing and breathing that significantly affects patient quality of life besides affecting their carer (Rogers, 2010; Terrell et al., 2004).

Medical practice has moved forward with special emphasis on the impact of the treatment provided towards patient‘s general well-being and not merely on the clinical progress (Basch et al., 2016). More importantly is how treatment nowadays can ease the negative experiences after the treatment and improve patient‘s overall quality of life of the patients besides increasing patients‘ satisfaction level, improving patients‘ psychological distress and involving minimal cost of resources involves (Velikova et al., 2004).

As the majority of patients are detected at late cancer stages (stage III and IV), (Doss, Thomson, Drummond, & Latifah, 2011) patients were always associated with poor prognosis and require more complex management (Chen et al., 2018; Gupta et al., 2016). Despite the increasing incidence, numbers of oral cancer survivors has been seen to be positively inclining (Velikova et al., 2004) possibly due to early detection, advancement in treatment and technology, and aggressive strategies in creating awareness among the population (Daigo et al., 2018; Rubin et al., 2015; Velazquez Berumen et al., 2018). While majority of oral cancer patients were reported among the elderly (Balasundram, Mustafa, Ip, Adnan, & Supramaniam, 2012; Parry, Kent, Mariotto, Alfano & Rowland, 2011), a more specific provision pertaining to individualised needs and concerns would allow a better prospective in health well-being (Parry, Kent, Mariotto, Alfano & Rowland, 2011).

The complexity of oral cancer disease and management has led to barriers in providing quality health management for patients and their family members (Rogers, El-Sheikha & Lowe, 2009). One of the barriers is the difficulty in understanding or identifying patients‘ concerns and their worries (Brandes, Linn, Smit, & van Weert, 2015). Quality of patient-clinician communication may be limited due to high volume of patients especially in a typical follow-up clinic in government hospitals which may compromise identifying patients‘ perspectives and psychological aspects (Mead & Bower, 2000). Variations in clinicians‘ communication skills may result in discrepancies in identifying patients‘ concerns that can lead to patients‘ unmet needs, underreporting their concerns and may also contribute to patients‘ reluctance in sharing their worries (Nur Fhatin Nadia Jasni, 2017; Baile & Aaron, 2005; Ha & Longnecker, 2010; Rogers, Clifford, & Lowe, 2011; Thorne et al., 2013).

1.3 Rationale of the study

Continuous improvements in managing oral cancer survivors have always been discussed and revised (NCCN, 2019). These suggests increasing positive outcomes among oral cancer survivors and to minimise knowledge gaps and research areas in cancer survivorship (Aziz, 2007). In recent years, patient-reported outcome measures (PROMs) (Rogers & Barber, 2017; Shunmugasundaram, Rutherford, Butow, Sundaresan, & Dhillon, 2019) and question prompt lists (QPL) (Miller & Rogers, 2018) have been of increasing interest to clinicians. The premise is that the patients' experiences and concerns can be used as indicators of their overall well-being and coping ability with their disease and treatment received (Foster, Croot, Brazier, Harris, & O'Cathain, 2018). These instruments are intended to maximise overall patients' outcomes at any phase of cancer management (Rogers & Barber, 2017; Sansoni, Grootemaat, Duncan, Samsa, & Eagar, 2014) to evaluate patients' satisfaction, improve patient-clinician communication and encourage shared decision making during a consultation (Chen, Ou, & Hollis, 2013). Routine use of prompt list has been shown to establish and monitor patients' outcomes especially on their quality of life (QoL) and psychological problems (Doss et al., 2017; Ghazali et al., 2015; Ghazali et al., 2017). However, assessing oral cancer patients' concerns, HRQoL and psychological distress are not routinely incorporated as part of the follow-up consultation protocol in Malaysia. This exclusion is because most HRQoL and psychological questionnaires are time-consuming, limited resources in health setting and tedious (Mead & Bower, 2000), thus leading to low compliance and sustainability.

Patient management has shifted towards a more patient-centred perspective in the health delivery process. Providing individualised patients centred approach is one of the tenets of patient-centred care which focuses on patients' overall well-being, their perceived need for healthcare, and their preferences for treatment and outcomes (Carr & Higginson, 2001). These patient outcomes have gained visible importance besides the traditional aim of disease outcomes (Carr & Higginson, 2001; Mead & Bower, 2000). Needless to say, clinicians will be able to provide good quality of care for patients through patients‘ involvement in decision making and further management from the multiple disciplinary team (MDT) (Barry & Edgman-Levitan, 2012).

Recently, another concept of shared decision making has been emphasized in healthcare management in Malaysia (Lum, 2018) which encourages patients‘ participation and personal engagement during consultation (Hawley & Morris, 2017). Facilitating patients to communicate or share their concerns is essential in limiting the gaps between clinicians and patients, and promoting their involvement during encounters with clinicians.

To address these issues, both patients and clinicians require a tool that is easy to be used, quick to be administered and more importantly relevant to the disease (Kanatas et al., 2013) that is deemed in a busy hospital setting (Mead & Bower, 2000). The prompt list should be able to assess patients‘ general state of health particularly their HRQoL and psychological problems and most importantly it should addresses the dental needs aspects as it is most affected by oral cancer patients (Shunmugasundaram et al., 2019). Such valuable information obtained would be able to guide clinicians on further management for better patient outcomes.

Rogers, El-Sheikha and Lowe (2009) had initiated Patient Concerns Inventory (PCI) for head and neck as an adjunct to improve patient's satisfaction, patient-clinician communication, shared decision making, uncovering patient's unmet needs as well as the clinical outcomes (Rogers & Barber, 2017). PCI is a prompt list of patients‘ concerns that they wished to discuss with the clinicians that act as a guide during patient-clinician consultation and to promote multidisciplinary care (Ghazali, Roe, Lowe, & Rogers, 2015). This prompt list could assist clinicians to provide or offer help to the patients as well as the family members (Foster et al., 2018). It was first introduced in the form of computer-assisted technology using a touch screen (TST) version (Rogers et al., 2009). PCI may be employed as a patient-reported outcome measure (as an item-specific prompt list) (Rogers & Barber, 2017), and as a communication tool to encourage question asking (as a QPL) (Miller & Rogers, 2018). The prompt list allows effective patient-clinician communication and assists clinicians in managing patients‘ care through an insight into patients‘ concerns or worries (Foster et al., 2018). However, environmental factors (eg pandemic outbreak of COVID-19) can restrict effective patient-clinician communication and can lead to barriers in addressing patients' unmet needs.

In Malaysia, PCI (Rogers et al., 2009) had been translated and cross-culturally adapted in 2014 (Hatta, Doss, & Rogers, 2014). The study used the paper version of PCI-H&N which consist of 43 items grouped into seven domains: physical status, emotional status, personal functions, social/family relationship, economic status, diet-related issues and others (Hatta, Doss, & Rogers, 2014). The present study used an adapted PCI-H&N, which is a combination of the latest version from Ghazali, Roe, Lowe, and Rogers (2015) and Hatta, Doss and Rogers (2014). This adapted list consisted of 52 specific concerns grouped into seven main domains of physical status, emotional status, personal functions, social/family relationship, economic status, diet-related issues, and others. The present study utilised two versions of the PCI-H&N, namely paper and a computerised web-based version.

As to date, there is one study conducted on PCI-H&N in the country (Hatta, Doss, & Rogers, 2014) on the paper version and another pilot study on the computerised web-based version (Doss et al., 2013, unpublished). Both studies found PCI-H&N to be feasible and as a simple holistic communication tool that improves patient- clinician communication in Oral Maxillofacial Surgery (OMFS) clinics for post-treatment oral cancer patients. However, almost 43% of the assistants perceived that PCI-H&N use disrupted the process of patients‘ registration (Hatta, Doss, & Rogers, 2014). Many other studies have shown a positive feedback on the computerised web-based version of PCI (Millsopp, Frackleton, Lowe, & Rogers, 2006; Norquist et al., 2017; Rogers, Pearson, & Lowe, 2017). However, little is known on the feasibility of computerised web-based version of PCI-H&N use in other local hospitals settings in Malaysia.

Realising the importance of monitoring health-related quality of life (HRQoL) and psychological problems among post-treatment oral cancer patients, there is a need to improvise on the normal routine of follow-up consultation. Newer approaches are needed to facilitate patients‘ involvement in decision making, to improve in patient-clinician communication during follow-up consultation, and to emphasise on individualised patient‘s approach for better patient satisfaction (Vartanian et al., 2017). However, there are limited studies available on this aspect and there is a need to further explore HRQoL and psychological distress of oral cancer survivors in Malaysia. Furthermore, the acceptability and the readiness for any new procedure from the perspective of both patients and health personnel is a paramount importance to ensure future sustainability (McNeil, 2011). Thus, there is a need to assess and establish mode of PCI-H&N and its appropriate mode that may be of optimal value for its implementation in oral maxillofacial clinics in Malaysia. It is believed that incorporating the PCI-H&N into routine follow-up consultation in OMFS clinics in Malaysia will help to minimise the gap of post-treatment oral cancer patients‘ unmet needs, provide a patient- centred care focuses and facilitates an effective communication for both patients and doctors, thus enhancing positive effects of patients care outcomes.

1.4 Research questions

- **i.** What are the post-treatment oral cancer concerns and number of items raised during their follow-up consultation?
- ii. Are there differences in patient health-related quality of life and psychological distress level before and post follow-up consultation among post-treatment oral cancer patients who used PCI-H&N and did not use PCI-H&N?
- iii. Are there differences in patient satisfaction with follow-up consultation among post-treatment oral cancer patients who used and non-use PCI-H&N?
- iv. Are there associations between patients‘ concerns and post-treatment oral cancer profiles, HRQoL, psychological distress level and patient satisfaction with follow-up consultation?
- v. Was PCI-H&N useful and feasible to be use routinely during follow-up consultation session?

1.5 Purpose of study

1.5.1 Aim

The aim of this study is to determine the feasibility of the PCI-H&N in assessing post- treatment outcomes in terms of HRQoL, psychological distress level and satisfaction among oral cancer patients during follow-up consultation.

1.5.2 Specific objectives

i) To identify post-treatment oral cancer patient concerns by using PCI-H&N (paper version & computerised web-based version) during follow-up consultation in terms of:

   a) types of concerns selected.
   b) number of the concerns selected

ii) To assess short term impact of PCI-H&N use and non-use on health- related quality of life and psychological distress levels among post-treatment oral cancer patients.

iii) To compare patient satisfaction with follow-up consultation among PCI-H&N users (paper version and computerised web-based version) and non PCI-H&N users (control).

iv) To investigate association of PCI-H&N domains and specific concerns among post-treatment oral cancer patients (in terms of number and types of concerns selected) with patients‘ details namely:

   a) patients‘ socio-demographic background
   b) patients‘ cancer characteristics
   c) patients‘ health- related quality of life.
   d) patients‘ psychological distress level.
   e) patients‘ satisfaction with post-treatment follow-up consultation.

v) To assess the usefulness and feasibility of PCI-H&N during the follow-up consultation in terms of:

   a) patients‘, clinicians‘ and assistants‘ feedback (Quantitative data)

b) time taken by the patients to complete the prompt list prior consultation session. (Quantitative data)

c) oral health personnel‘s experiences in the implementation process. (Qualitative –FGD information)

d) suggestions for improvement of PCI-H&N implementation. (Qualitative –FGD information)

1.6 Alternative hypothesis

i. There are significant differences between both PCI-H&N versions (paper and computerised web-based) in terms of types and number of concerns selected.

ii. There are significant differences in patient health-related quality of life and psychological distress level at baseline and 1-month time point among the PCI-H&N user and non-user.

iii. There are significant differences in patient satisfaction with follow-up consultation between groups who use PCI-H&N (paper and computerised web-based version) and non PCI-H&N use.

iv. There are significant differences in the association between PCI-H&N concerns selected by socio-demographic background, cancer characteristics, health-related quality of life, psychological distress level and patient‘s satisfaction.

v. There are significant differences in terms of feasibility scores between the two PCI-H&N versions (paper-based PCI and computerised web-based version).

1.7 Conceptual framework of the study

The concept of this new procedure is to be incorporated during post-treatment follow-up review. Barriers faced by the patients and clinicians during the follow-up consultation are influenced by few factors namely from the patients‘ perspectives, the clinicians and the environment of the hospitals. The concept was introduced to minimise the gaps between patients and clinicians for better health quality care by improving patient-centred care, enhancing patient-clinician communication and encouraging multidisciplinary approach. Considering these factors, it is postulated that the new procedure of introducing the PCI-H&N during follow-up consultation can improve patients‘ outcomes namely HRQoL, satisfaction with the follow-up consultation, psychological distress level, and optimise the consultation time between clinicians and patients. Subsequently, it is also aimed to improve the service delivery system for patients‘ benefit by optimising a suitable delivery mode of PCI-H&N and using available resources. However, there are other factors contributing to the intended outcomes including patients‘ socio-demographic, cancer and treatment- related characteristics.

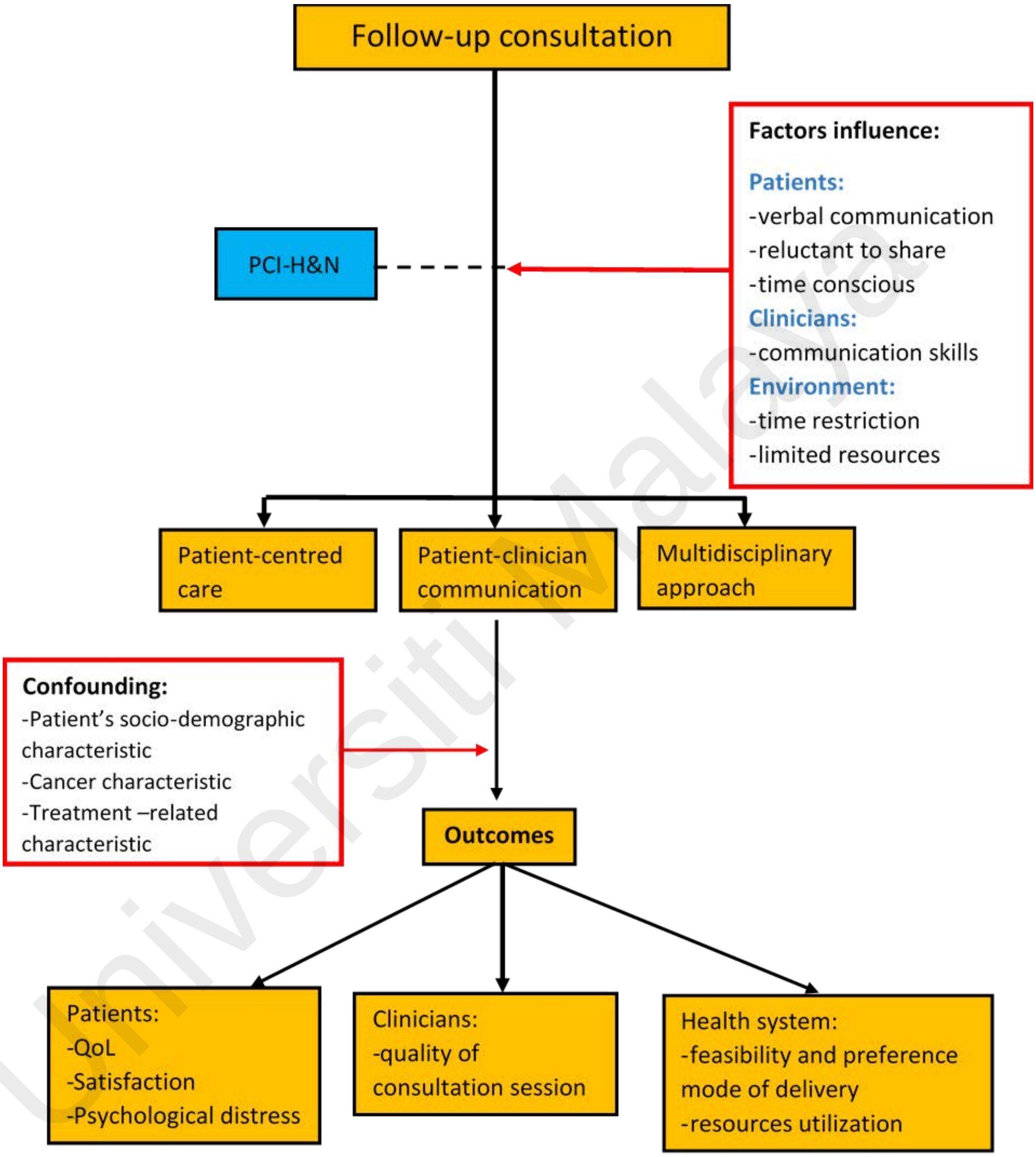

Figure 1.1: Conceptual framework of present study

CHAPTER 2: LITERATURE REVIEW

2.1 Oral cancer

2.1.1 Epidemiology of cancer

Cancer is a global public health issue. The GLOBOCAN 2018 report of cancer incidence and mortality produced by the International Agency for Research on Cancer (IARC) had estimated that cancer would be the leading cause of death in the 21st century (Bray et al., 2018). The latest data from GLOBOCAN in 2018 reported that 18.1 million of new cancer cases had been diagnosed with 9.6 million of deaths, and over one-half of the cancer deaths in the world would occur in Asia in the year 2018 (Bray et al., 2018). In Malaysia, a total of 103 407 new cases of cancer were diagnosed in the country within the five years from 2007 to 2011 (Azizah, Nor Saleha, Noor Hashimah, Asmah, & Mastulu, 2016).

2.1.2 Epidemiology of oral cancer

Head and neck cancer can occur in more than 30 different areas of mucosal lining commonly found at the oral cavity, oropharyngeal, salivary gland, larynx, thyroid gland, ear, and excluding the eyes and central nervous system (Davies & Welch, 2006). About 90% of head and neck cancers are cancers of the lip, oral cavity, nasopharynx, and pharynx (Bagan & Bagan-Debon, 2020). WHO has published a standard classification to define cancer site; the International Classification of Diseases for Oncology (ICD-O). Oral cancer sites are coded as ICD-10 code C00-06: lip, oral cavity as classified by the latest classification version of ICD-10 Version: 2019 (WHO website, retrieved 2020).

Cancer of the oral cavity affects mainly the tongue (usually at the posterior lateral site) in males and among the elderly and is often related to lifestyle habits (tobacco- or alcohol-related) (Scully & Bagan, 2009). Cancer of the tongue is mostly detected at an advanced stage III or IV (Scully & Bagan, 2009). Oral cancer is prominent among men all around the globe (Bray et al., 2018); however, there is an increasing trend among females in developing countries (Curado & Hashibe, 2009). In South-East Asian (SEA) countries, the incidence of oral cancer was highest in Myanmar for males and among females in Brunei (Cheong et al., 2017).

Oral cancer can be classified according to the staging of the International Union Against Cancer‘s classification system, as shown in Table 2.1.

Table 2.1: Cancer staging according to the International Union Against Cancer's classification system

Cancer staging	**TNM**
Stage I	T1 N0 M0 x
Stage II	T2 N0 M0 x
Stage III	T3 N0, T1-3 N1, and M0 x
Stage IV	T4 any N, T1-3 N2-3, any T any N M1

Globally in 2017, 890 000 new cases of head and neck cancer were estimated by the Global Burden of Disease, of which 5.3% represented all cancers. In terms of mortality, 507 000 deaths due to HNCs had been reported, also representing 5.3% of all cancer deaths, the same percentage as the new cases (Collaboration, 2019). Incidence of the lip and oral cancer has increased tremendously from 186 000 (95% UI: 192–180) in 1990 to 390 000 (95% UI: 404-374) in 2017, and remained high compared to other cancers of head and neck, and still higher in males than females (Du, Nair, Jamieson, Liu, & Bi, 2020; Lin et al., 2019). South Asia has the highest incidence rate of oral cancer, followed by North America, Europe, and Australasia (Bray et al., 2018; Lin et al., 2019).

Oral cancer was ranked as the fourth most common cancer among South-East Asia Region (SEARO) as reported in GLOBOCAN 2018 (Bray et al., 2018). Although there was an increasing trend in ASEAN countries, a few countries such as Singapore, Thailand, and the Philippines have shown decreasing trends (Ferlay et al., 2015) According to the latest GLOBOCAN data published in 2018, oral cancer incidence in Malaysia was 667 of new cases with 327 deaths, and according to World Health Ranking website (2018), Malaysia ranked 60 out of 183 countries and at a death rate of 4.29 per 100 000 people (age-standardised). Cancer of the oral cavity is higher among men with a male-to-female ratio of 1.4:1 and it is projected that oral cancer incidence would continue to rise with increases of up to 31.1% and increase of 32.8% of mortality (Cheong et al., 2017). Cancers of the lip and oral cavity are highly frequent in Southern Asia (i.e India and Sri Lanka) as well as the Pacific Islands (Papua New Guinea, with the highest incidence rate worldwide for both sexes), and it is also the leading cause of cancer death among men in India and Sri Lanka (Cheong et al., 2017).

Notably, when we look at the incidence of oral cancer across the world, three of the SEA countries were among the top 20 countries with the highest incidence of oral cancer, e.g. Myanmar, Brunei and Cambodia for both genders. Countries with the highest incidence of oral cancer among females were Brunei, Timor-Leste, Cambodia, Lao PDR and Myanmar (Cheong et al., 2017). Head and neck cancer has been reported in most studies to be more prevalent in people with low socioeconomic status. This observation might be related to the accessibility of health care facilities and low awareness of the disease (Gilyoma, Rambau, Masalu, Kayange, & Chalya, 2015). Studies had found that the high incidence and death in the low-income and middle-income countries were due to high tobacco consumption (Bray et al., 2018; Bray & Soerjomataram, 2015; Ghani, Razak, et al., 2019).

Incidence of oral cancer varies substantially by demography, race and ethnicity. Malaysia has a multi-ethnic population, and oral cancer is highly reported among Indians and the indigenous population. According to the National Cancer Registry (2007-2011), Ministry of Health (Malaysia), mouth cancer is the cancer common among the Malaysian Indian community and frequently reported among Indian females (Azizah, Saleha, Noor Hashimah, Asmah, & Mastulu, 2016). Indigenous ethnic groups from Sabah and Sarawak have been identified as a high-risk group for oral cancer. Incidence of oral cancer had been highly reported among the elderly (Bray et al., 2018). However, the trend now has shown as occurring more frequently in the younger age group (Ram et al., 2011).

Majority of newly diagnosed oral cancer cases were at advanced stages (stage III and IV) (Doss, Thomson, Drummond, & Latifah, 2011; Gilyoma et al., 2015). This finding was supported by Doss et al. (2011), where the study had found that 67.1% of oral cancer cases were diagnosed at a late stage and needed more complex management. In addition, Balasundram et al. (2012) had reported that for oral cancer diagnosis of one and three years, the overall survival rate was 72.7% and 61.6% respectively. Prognosis of oral cancer disease becomes poor with late clinical detection, and more complex management will be needed further (Chen et al., 2018; Gupta et al., 2016). Thus, more issues and patients‘ concerns will need to be focussed and tackled to increase the positive outcomes of oral cancer survivors. Better outcomes are expected in patients diagnosed at the early stage of cancer, but the majority of oral cancer patients are diagnosed at an advanced stage (stage III and IV) (Balasundram, Mustafa, Ip, Adnan, & Supramaniam, 2012; Doss et al., 2017a). Complex oral cancer treatments include surgical with a combination of adjuvant treatment of radiotherapy with or without chemotherapy, mostly a treatment option for the late cancer stage which is related to poor post-treatment outcomes (Doss et al., 2017a; Rathod, Livergant, Klein, Witterick, & Ringash, 2015).

Early detection at an early stage of oral cancer (stage I and II) can improve successful treatment provided and increase positive chances of outcomes for survival (Gilyoma et al., 2015). Patients tend to deny their oral cancer disease signs and symptoms, and presume it as a minor condition that needs no immediate treatment (Nurizyani Azhar, 2017). This denial could be possibly due to patient anxiety that delays the patient in seeking oral cancer diagnosis which can contribute to late diagnosis and influence the poor prognosis of patients‘ 5-year survival (Nandra & Aiyegbusi, 2020). The lower socioeconomic background patients failed to interpret the symptoms mostly due to lack of knowledge and awareness regarding oral cancer (Nurizyani Azhar, 2017).

Even so, there are a positive increase of cancer survivors as part of successful oral cancer cases that have been detected (Siegel et al., 2012; Velikova et al., 2004) due to the advancement in oral cancer detection, vast improvement of treatment and technology in medical perspective, and forceful strategies in creating awareness among the population (Daigo et al., 2018; Miller et al., 2019; Rubin et al., 2015; Velazquez Berumen et al., 2018). Improvement in the number of long-term cancer survivors requires health and service provision that caters more to individualised patients‘ related concerns such as a better perspective of understanding and addressing their issues especially when the majority of the survivors are among 65 years age of the population (Parry, Kent, Mariotto, Alfano, & Rowland, 2011). All cancer survivors undergo comprehensive follow-up reviews and generally the follow-ups are every one to three months in the first year, two to six months in the second year and four to eight months within three to five years (Cervenka et al., 2019).

2.1.3 Aetiology and pathology of oral cancer

Oral cancer is a ―multistep process to metastasize to other tissues of the body in which genetic events lead to the disruption of the normal regulatory pathways that control basic cellular functions including cell division, differentiation, and cell death" (Webster's New World Medical Dictionary, 3rd Edition, 2009; Williams, 2000). Alternatively, according to Jain (2019), ―it is a multistep process in which genetic events within signal transduction pathways governing normal cellular physiology are quantitatively or qualitatively altered". In general, the disruption of cell proliferation is due to damage to the DNA, which leads to genetic changes of Oncogenes, Tumour suppressor genes, metastasis genes and DNA repair genes (Syafriadi, 2008).

There are many variations of head and neck cancer, and the majority (~ 90%) are of oral squamous cell carcinomas (OSCC) (Ferlay et al., 2015; Pai & Westra, 2009). Other than SCC, head and neck cancer may also develop from other types of cells such as cells of the lymphatic system, lining cells of the glands, melanocytes, and cells of the muscles, cartilage or blood vessels (Gilyoma et al., 2015). Oral cancer can progress from its pre-malignancy/benign or known as oral potentially malignant disorders before progressing into invasive carcinoma of a malignancy phase. In 2005, WHO renamed the premalignant lesions as ―oral potentially malignant disorders" (OPMDs), a term that suggests malignant transformation may not be an inevitable consequence, rather a possibility, and may occur at a site distinct from the original presenting lesion (Goodson, 2019). Main conditions of OPMDs include oral leukoplakia, oral erythroplakia, oral submucous fibrosis, oral lichen planus, and actinic cheilitis (Dionne, Warnakulasuriya, Zain, & Cheong, 2015; Thomson, 2012). Previously, lichen planus was also associated with OPMDs; however, it remains as controversial since it was reported as low malignancy transformation rate (0.2- 1.0%) (Dionne et al., 2015). These chronic conditions may precede the development of oral squamous cells carcinoma (Mello et al., 2018) that need clinical attention during dental screening for early detection.

2.1.4 Risk factors for oral cancer

As to date, the exact cause of cancers is unknown, but there are many risk factors that are considered to be multifactorial. Oral cancer can be due to many predisposing factors that can be divided into intrinsic (hereditary) and extrinsic factors (bacteria, viruses, fungi, chemical, drugs, radiation, trauma, heat, cold and nutrition). There are cases where oral cancer developed in patients without known risk (Schantz & Yu, 2002).

Globally, the most common risk habits that are highly associated with oral cancer are chemical risk factors (Cheong et al., 2017; Miranda-Filho & Bray, 2020). Chemical risk factors such as tobacco products (smoked and smokeless product such as snuff, chewing tobacco or placing between the gum and the cheek or lip), alcohol consumption, and betel nut (a mixture of tobacco, areca nut, and other ingredients, e.g. lime, spices) chewing are well established as the carcinogenic effect of oral cancer (Aupérin, 2020; Ghani, Razak, et al., 2019; Ram et al., 2011; Thomson, 2012; Zain, 2001). In Malaysia, these habitual factors are highly associated with multi-ethnicity practices (Ghani, Razak, et al., 2019; Maling, Doss, & Low, 2018). Smoking habit was most common among the Malays, while the Chinese‘s regular habits were smoking and drinking (Ghani, Razak, et al., 2019). Whereas, betel quid chewing was found more customary in Indians and Indigenous ethnicity practising risk habit for oral pre-cancerous and cancerous lesions and the highest prevalence of oral cancer was among the Indians (Ghani, Razak, et al., 2019). Ghani, Razak, et al. (2019) found that all three risk habits were frequently practised among the Indigenous community. Some studies have shown a significant association of developing higher risk of head and neck cancers when patients were exposed to alcohol and tobacco together (Smith, Rubenstein, Haugen, Hamsikova & Turek, 2010; Warnakulasuriya, 2010).

Betel quid chewing was more highly at-risk habit to develop oral cancer (six times increased risk), followed by smoking with three times and four to five times at risk of oral cancer among those who smoke and also consume alcohol, respectively. A higher risk of developing oral cancer was observed among those who were practising more than one risk habit (Ghani, Razak, et al., 2019).

The role of smoking, alcohol consumption and betel quid chewing as a risk factor for oral cancer has been established by numerous researchers (Nagao & Warnakulasuriya, 2020). Besides these habitual factors, another risk factor is the virus which modifies the DNA structure and causes proliferation. Most common viruses associated with oral cancer are Human Papillomavirus, Herpes Simplex Virus and Epstein - Barr virus (Chaitanya et al., 2016). In recent years, human papillomavirus (HPV) infection has been highly reported to influence the carcinogenesis of oral cancer (Aupérin, 2020). A previous study has reported that a recent increase in oral cancers at the base of the tongue was associated with the human papillomavirus (HPV) and it was highly observed in white men in the United States (Saba et al., 2011).

2.2 Current concepts of oral cancer approach

Patients‘ outcomes and impacts from oral cancer and its treatment among oral cancer patients have gained visible importance besides the traditional aim of disease outcomes (Carr & Higginson, 2001). As such, many initiatives have been undertaken to improve patients‘ experience with healthcare facilities and the professionals (Carr & Higginson, 2001; Nandra & Aiyegbusi, 2020; Rogers et al., 2009). WHO has published a series of guidance for effective cancer control programmes starting from planning, prevention, beginning of new procedures, diagnosis and treatment, palliative care, policy and advocacy. It stated that ―*there is a need to focus on responding to the needs of people at risk of developing cancer or already presenting with the disease, in order to meet the patients" physical, psychosocial and spiritual needs across the full continuum of care*" (World Health Organization, 2007).

Therefore, it is of great value to provide an individualised measure on the quality of life. It can be recognised as being patient-centred, as it reflects patients‘ perspectives of their disease and treatment, their perceived need for healthcare, and their preferences for treatment and outcomes (Carr & Higginson, 2001). Clinicians will be able to provide good quality of care to the patients through multiple disciplinary teams (MDT) and shared decision making (Barry & Edgman-Levitan, 2012). Improvements in cancer patients‘ approach had been widely discussed in many studies, especially during follow-up reviews (Morgan & Yoder, 2012; Nandra & Aiyegbusi, 2020; Wells et al., 2015). These concepts are widely accepted not only due to the impact on patients physical impact, HRQoL and psychological distress, but also in helping patients to adopt the ‗new possibility‘ of daily life after completing their cancer treatment (Ottosson, Laurell, & Olsson, 2013; Rennie, Stoddart, & Hubbard, 2018). The concepts mentioned in this section are all related to the study intervention, i.e. PCI-H&N.

2.2.1 Patient-centred care

Patient management has shifted towards a more patient-centred perspective in the health delivery process. Implementing patient-centred care is an essential attribute of a positive outcome of quality care (Baker, 2001). However, the implementation of this approach has not been widely implemented despite evidence on its benefit and health policy recommendations (Coulter & Ellins, 2006).

Patient-centred care (PCC) is an approach of caring for patients (and their families) in ways that are meaningful and valuable to the individual patient by listening to, informing and involving patients in their health care management. The IOM (Institute of Medicine) defines patient-centred care as ―*providing care that is respectful of, and responsive to, individual patient preferences, needs and values, and ensuring that patient values guide all clinical decisions"* (Baker, 2001). Meanwhile, Morgan and Yoder (2012) have included the element of patient empowerment and shared decision making in the earlier definition as *"a holistic (bio-psychosocial-spiritual) approach to delivering care that is respectful and individualized, allowing negotiation of care, and offering choice through a therapeutic relationship where persons are empowered to be involved in health decisions at whatever level that is desired by that individual who is receiving the care".* The Picker Institute identified eight domains in promoting PCC: (i) respect for patient's preferences and values; (ii) emotional support; (iii) physical comfort; (iv) information, communication and education; (v) continuity and transition; (vi) coordination of care; (vii) involvement of family and friends, (viii) and access to care (Gerteis, 1993).

Health care and quality measurement based on patient-centred care concepts focus on individual patients' needs, the health outcomes and healthcare provider approach in health management (Bergeson & Dean, 2006). One of the keys to providing patient-centred care is increased patients‘ participation in decision making by encouraging patients to express their needs and concerns. Other vital elements are improving access to and continuity with clinicians, supporting patient empowerment of self-care and establishing more efficient and reliable health care mechanism (Bergeson & Dean, 2006).

2.2.2 Holistic patient approach

In some studies, holistic care is recognised as part of achieving patient-centred care (Tjale & Bruce, 2007). Holistic care can be described as a behaviour that recognises and values whole persons as well as the interdependence of their parts (McEvoy & Duffy, 2008). Tjale and Bruce (2007) described holistic care as *“a behaviour that recognizes a person as a whole and acknowledges the interdependence among one's biological, social, psychological, and spiritual aspects. Holistic care includes a wide range of approaches, including medication, education, communication, self-help, and complementary treatment”* (Tjale & Bruce, 2007).

This approach was deemed appropriate for newly diagnosed patients with head and neck cancer as it is well accepted that adverse effects from the cancer treatment cannot be avoided and it affected the patients‘ quality of life (Bower, Vlantis, Chung, & Van Hasselt, 2010).

2.2.3 Individualised patient care

Individualised patient care has been widely emphasised, mainly in nursing care (Redfern, 1996). Previously, disease-based approach viewed patients as ―cases” rather than individuals as in the individualised patient care which is more ―humanly” (Green, Carrillo & Betancourt, 2002). Hence, this concept not only focuses on patients‘ needs, preference and satisfaction but also associated with patients‘ perception, experience and feelings (Acaroglu & Sendir, 2012). This concept has been applied in achieving patient-centred care through various interventions and approaches in health settings by integrating new procedure in managing patients (Butow et al., 1996; Redfern, 1996; Rogers et al., 2009). Providing individualised patient care is one of the tenets of patient-centred care which focuses on patients‘ overall well-being, their perceived need for healthcare, and their preferences for treatment and outcomes (Carr & Higginson, 2001).

With the challenges of meeting patients‘ demands for better outcomes, health management has diverted from the conventional approach of disease-based treatment to accommodate an individualised patient approach in their patient management (Bowling & O'Hare, 2012; Green et al., 2002). However, individualised patient approach needs to align with the disease-based treatment strategy to achieve the best outcomes (Bowling & O'Hare, 2012).

2.2.4 Shared decision making

A newspaper article dated 27th May 2018 highlighted the importance for healthcare providers to establish personal engagement with patients and family members (Lum, 2018). The article emphasised on a patient-doctor relationship and shared decision making in healthcare. Since its introduction in 2012, this concept has grown in its acceptance and practice in Malaysia. This concept is relatively new in Malaysia, and it is slowly showing its importance since 2010. Shared decision making in Malaysian context is relatively unique due to the multicultural society and the diversity of its ethnic components (languages, medical paternalism, strong family involvement, religious beliefs and the practice of complementary medicine) (Lee & Ng, 2017). This concept has gained recognition from the Ministry of Health, Malaysia and many strategies have been implemented towards it. Part of the initiatives is the introduction of a guideline by Malaysian Medical Council on doctor-patient relationships and patient satisfaction through shared decision making, which has been emphasised as one of the four health outcomes under the national policy blueprint known as the 11th Malaysia Plan, 2016-2020 (Economic Planning Unit, 2015). The main challenge in engaging patients in the shared decision making is the multi-languages which affect patient-clinician communication (Lee & Ng, 2017).

2.2.5 Multidisciplinary team approach (MDT)

Most of the oral cancer patients will endure a life-long impact; from the time of diagnosis until life ends (Sanft et al., 2019). The increasing number of oral cancer survivors has created new challenges to the clinicians in providing the best quality of care to them. It requires collaboration and coordination of expertise from various disciplinary areas in managing the effect from the cancer disease and the treatment received. The complexities of these impacts require total patient care approach from a multidisciplinary team, mainly consisting of dental specialists and oncologists, as well as other allied health care professionals, namely speech therapist, nutritionist, social health workers, rehabilitation, and others (Licitra, Felip, & Group, 2009; Reddy, 2017; Samim, Epstein, Zumsteg, Ho & Barasch, 2016).

Collaboration from multiple specialities enables optimised patient care as different experts share their inputs to ensure best quality care to the patients and at the same time promotes continuous professional development (Rocke et al., 2020). The concept of advocacy was introduced among the head and neck cancer patients and the clinicians by the MDT head and neck cancer team as it brings benefit to patients and improves positive outcomes by raising awareness and educating clinicians regarding the needs of cancer survivors (Dawson et al., 2020).

In a qualitative study, integration of multiple health personnel in head and neck cancer patient management at all the survival phases; pre-diagnosis, post-diagnosis, during treatment, post-treatment and into prolonged survivorship; had demonstrated good coordination of patients‘ appointments arrangement between multiple clinics that eased patients‘ burden in attending the follow-ups (Brady, Goodrich & Roe, 2020; Findlay, Rankin, Bauer, et al., 2020). As such, MDT could prevent patients from attending multiple follow-up appointments on different days (Coulter & Ellins, 2006). Much attention has been given to reduce the negative impact of post-treatment outcomes on patients‘ dietary intake that could lead to malnutrition. Involvement of multidisciplinary experts can improve and provide better quality patients‘ management (Findlay, Rankin, Shaw, et al., 2020).

2.2.6 Patient management during the pandemic outbreak

At the time of this write up, the world is faced with a global pandemic outbreak of coronavirus disease 2019 (COVID-19) (WHO website, 2020). COVID-19 has a great impact on all population and patient management is affected by its highly contagious nature. This situation has forced the health management to find alternative methods to ensure a continuum of patient care throughout this difficult time (Kanatas & Rogers, 2020). Many alternative approaches are using telemedicine as a mode of patient management which has grown a great acceptance from patients and clinicians (Prasad, Brewster, Newman, & Rajasekaran, 2020). However, not all cancer patients can be managed through this method. As such, the patient selection was based on their prioritisation and the types of management required (Hanna, Evans, & Booth, 2020). Therefore guidelines and recommendations in managing cancer patients has been developed to provide standard of patients care during this pandemic outbreak (NCCN website, 2020; Bann et al., 2020).

In terms of the post-treatment oral cancer patients‘ follow-up consultation, employing a virtual mode of consultation is deemed to be feasible in providing a quality of patient care especially in the current pandemic situation (Prasad et al., 2020). In a recent study conducted by Kanatas and Rogers (2020), the follow-up consultation among the post-treatment oral cancer patients were performed through phone consultation between patients and their clinicians. The flexibility of the PCI prompt list for head and neck cancer (Rogers et al., 2009) enables the clinicians to address patients‘ unmet needs to suit any situation that restrict patients from having a normal face-to-face consultation with their clinicians (Kanatas & Rogers, 2020).

2.2.7 Current patient approach practiced in Malaysia

In Malaysia, the concept of oral cancer patient management has been influenced and shaped by our local Eastern cultural upbringing and is reflective of the traditional approach/practice demonstrated by the clinicians as the result of medical/ dental school curriculum. The Easterners are more conservative and do not openly or willingly share their thoughts with other people that are not close to them. The inquiry or information seeking usually obtained through close-ended questions and more often than not clinicians need to probe further with questions for more information (Susan, 2013).

Personalised patient care has been a good practice among the clinicians in OMFS, Malaysia. Personalised care is delivered by the same team of clinicians involved in the patient‘s management from the diagnosis phase right through to post treatment follow-ups. As such, a good rapport and trust between patient-clinicians and family members is established (NHS England, 2019) and this can increase the quality of patient care as there is consistency in the follow-up session.

In Malaysia, the tertiary Oral and Maxillofacial referral centres for oral cancers have been identified by MOH. They are located in hospitals with adequate multidisciplinary units that is able to provide a holistic patient management. However, the function and its utilisation as a team in managing oral cancer patients is not well described (Alobaidi, Doss, & Abmurat, 2018; Aznilawati, 2017).

2.3 The challenges in providing quality patient care for post-treatment oral cancer patients

There are many challenges in managing oral cancer patients. The impact of oral cancer disease and its treatment on patients‘ quality of life create barriers in providing better health management to the patients, family and caretakers. The barriers between patients and clinicians restrict the clinicians from understanding what the patients‘ concerns and their worries are (Brandes, Linn, Smit, & van Weert, 2015). The barrier between patients and doctors as well as other healthcare professionals has an impact on providing the best options for the best outcomes and better quality of life (Rogers et al., 2009).

Barriers faced by the patients and clinicians during the follow-up consultations are influenced by a few factors, namely from the patients‘ perspectives, the health providers and the environment of the hospitals.

2.3.1 Patients' perspective

The biggest challenge among clinicians is addressing patients‘ unmet needs as it can create an underreporting of concerns (Nur Fhatin Nadia Jasni, 2017; Baile & Aaron, 2005; Ha & Longnecker, 2010a; Thorne et al., 2013). Assessing patient‘s unmet needs can be addressed at these three key stages of patient management: (i) during cancer treatment, (ii) immediately after the treatment and (iii) into survivorship (Harrison, Young, Price, Butow, & Solomon, 2009). Patients have different concerns and worries at different points of treatment stages which require different approaches in addressing their concerns (Byrne & Rogers, 2017; Kanatas et al., 2013). This information seeking ability may facilitate patients and their family members to inquire further information on the cancer related issues: cancer diagnosis, the treatments and recovery post-treatment (Byrne & Rogers, 2017).

Another great challenge in gaining the information needed is the language barrier. Malaysia is known for its multi-languages with different dialects due to its multi-ethnicity composition. It would be an advantage if there is assistance in translating the language to make both parties; the patients and the clinicians understand each other better. Alternatively, the clinicians need to learn different languages in order to have a quality patient-clinician communication (Susan, 2013).

As the number of survivors increase, the existing current models of care will be increasingly inadequate to meet their needs. Variation of patients' unmet needs is influenced by cancer site, stage, treatment type, and time from treatment completed in which immediate post-treatment phase is affected more compared to long-term survivorship (Shunmugasundaram et al., 2019). Most commonly affected post-treatment patients is the eating function, which affects patients' nutritional needs with a higher impact among those on PEG tube (Findlay et al., 2020). Inability to address patients' unmet needs could lead to a negative outcome if left neglected (Shunmugasundaram et al., 2019). Nutrition needs among post-treatment head and neck cancer are complicated, which require advice from the expertise of multidisciplinary team members (Findlay et al., 2020). Exploration of new strategies and models of care to better address quality-of-life issues and meet the needs of survivors of head and neck cancer is urgently required (Ringash, 2015).

Nur Fhatin Nadia Jasni (2017) had conducted a mixed-mode pilot study among oral cancer patients in three OMFS hospital based in Malaysia (two MOH hospital-based OMFS clinics and one teaching hospital OMFS). The study had identified a few issues related to unmet needs which need to be addressed by healthcare providers. Some of the main findings were: 31.8% had lack of energy and tiredness, 28.8% were concerns of worries of those close to the patients, 28.8% were fearful about the cancer spreading, 25.5% were in pain, and 18.2 % had anxiety (Nur Fhatin Nadia Jasni, 2017).

The reluctance in sharing their concerns and worries are not uncommon, especially among the eastern population (Hatta, Doss & Rogers, 2014). To reveal personal and intimate issues would be a great embarrassment to the patients, even if it is meant for health purposes. This reticence leads to difficulties in understanding or identifying patients‘ concerns and their worries (Brandes et al., 2015; Hautamäki, Miettinen, Kellokumpu-Lehtinen, Aalto, & Lehto, 2007; Rogers, Hazeldine, O‘Brien, Lowe, & Roe, 2015; Ussher et al., 2013), especially in Malaysian culture (Hatta, Doss & Rogers, 2014). Also, the physical impact due to the cancer treatment, for example, tongue dissection would make patients‘ speech challenging to be understood, making it difficult to achieve good patient-clinician communication (Weatherspoon, 2017).

Patients who had been waiting for a long period tend to unveil their concerns to the clinicians. Long waiting time at the clinic created time-consciousness among the patients who sometimes want to shorten the consultation session and were reluctant to participate in the discussion (Rogers, 2009). Majority of oral cancer patients are among the elderly who depend on their carers, who are mostly their children, to bring them to the clinics (Hatta, Doss & Rogers, 2014), and this could be one of the reasons for them to want a quick consultation session.

2.3.2 Health provider’s perspective

Variations in clinicians‘ communication skills may result in discrepancies in identifying patients‘ concerns. Clinicians may develop this skill through the learning process and daily practice among the patients (Coulter & Ellins, 2006). Many studies had shown the importance of patient-clinician communication in improving patients‘ outcomes and well-being (Baile & Aaron, 2005; P. N. Butow et al., 1996; Nielsen, Mehlsen, Jensen, & Zachariae, 2017). It was also observed that improved patient-centred communication might create a positive influence on their emotional aspects (Nielsen et al., 2017).

With the high patient volume in hospitals, clinicians are hard-pressed to achieve optimal outcomes from their communication with patients during limited consultation sessions (Brandes et al., 2015; Mead & Bower, 2000). Often, this results in patients‘ unmet needs not being addressed accordingly, more so if patients are unwilling to voice their concerns due to various cultural and communication barriers (Ha & Longnecker, 2010; S. Rogers, Clifford, & Lowe, 2011; Thorne et al., 2013). Significant barriers related to health providers concerns the healthcare provider‘s behaviour of which a study has shown that some health providers did not involve the patients to discuss their concerns, did not show their empathy to the patient and did not provide enough information to reduce the patients‘ concerns (Brandes et al., 2015). Whereas, a study conducted in a teaching hospital in Kuala Lumpur revealed that poor communication is negatively associated with patient satisfaction and the quality of care among cancer patients due to variation of communication skills and gaining experiences of the clinicians (Ezat, Fuad, Hayati, Zafar, & Kiyah, 2014).

Employees are the most valuable asset to any sectors, and they can be the most influential factor in making any intervention a success. A systematic review had highlighted that the biggest challenge in an organisation to deliver quality patient care is their staff (Geerligs, Rankin, Shepherd, & Butow, 2018). The study reported that lack of time and staff-related barriers (such as staff workload, high turnover, rotation of duty, attitudes and their commitment) are essential aspects that need to be overcome by the organisation in providing a quality patient care (Geerligs et al., 2018). These challenges were also highlighted in a study conducted by (Teh & Pung, 2017) as they assessed the factors that could contribute to involvement in their research. The main challenge of any initiative‘s implementation mainly depends on the clinicians‘ motivation and factors encouraging their participation in conducting it. The same study surveyed the specialists to assess their participation in research involvement, and it was found that their involvement depends on if it highly benefits the patients (98.9%), and helps with their career development (93.3%). However, their involvement in the research was determined by the conveniences of their present working condition which could determine future participation of other implementation of an intervention or continuation of the present intervention (34.8%) (Teh & Pung, 2017).

The importance to establish a good patient-clinician communication is not something new in health care. A comprehensive, effective and efficient communication can be achieved in many ways. In some studies, this concept is referred to as a patient-centred communication, which involves focusing on the patient‘s needs, values and wishes (Epstein, Mauksch, Carroll, & Jaen, 2008). Various methods had been discussed in achieving these principles. Some practices used the written or online form of patients‘ needs, which the patients will complete it either at home or in the waiting area before they attend the scheduled appointment. Others used a similar method of completing the form but with a listed of a general questions pertaining on their possible problems; e.g. ―would you able to do your daily chores?‖. Still, another approach uses medical assistants or trained patient coaches to help the patients identify and prioritise their concerns (Epstein et al., 2008).

2.3.3 Environment/ External perspective

The presence of many patients in typical follow-up clinics is not unusual, especially in government hospitals. In the limited consultation time available for each patient, clinicians face many barriers, such as unmet needs, patients underreporting their concerns, thinking about the many patients waiting outside the clinic, difficulty in communication due to effect from the cancer treatment or because patients are reluctant to share their worries (Rogers et al., 2011). The quality of patient-clinician communication may be affected due to the high volume of patients, especially in a typical follow-up clinic in government hospitals, which may compromise identifying patients‘ perspectives and psychological aspects (Mead & Bower, 2000).

2.4 Outcomes of post-treatment oral cancer patients

The present study was conducted among oral cancer patients who had completed their oral cancer treatment/s. The treatments was either be surgery only, radiotherapy/chemotherapy without surgery or a combination as it varied according to the cancer characteristics: sites, size, TNM staging (Colevas et al., 2018; Dionne et al., 2015). The term used to describe the study population was post-treatment oral cancer patients and not oral cancer survivors. This is because the NCCN Survivorship Panel‘s definition of cancer survivor is ―*an individual is considered a cancer survivor from the time of diagnosis, through the balance of his or her life. Family members, friends, and caregivers are also impacted and included in this definition and are therefore included in this definition.”* (Institute, 2012). Post-treatment oral cancer patients are those who had completed their cancer treatment (Merriam-Webster, 2020) and on follow-ups.

Although oral cancer is not among the global leading cancers compared to other cancers (e.g. lung, breast, prostate, colorectal, stomach and liver) but the impact of the disease and its treatment can possess a hugely detrimental effect on physical, emotional, social, psychological function and patients‘ HRQoL (Brown & Yabroff, 2006; Ghazali et al., 2015; Stewart & Wild, 2014; Weymuller Jr et al., 2000). Effect of the cancer disease and its treatment often lead to long-term impacts to the patients (Peach et al., 2018; Rathod et al., 2015).

Besides that, they are also subject to economic aspects either as individuals, their caretakers or to the general public due to high treatment cost, possibility of permanent impairment and higher mortality rate (Massa, Osazuwa-Peters, Boakye, Walker, & Ward, 2019; Reichart & Way, 2006). The impact varies individually according to the cancer stages, site of cancer, treatment-related issues, patients‘ age and social background (Razak, Saddki, Naing, & Abdullah, 2010; Rogers et al., 2009; Vartanian, Rogers & Kowalski, 2017).

In current medical practice, the outcomes of clinical management are not merely measured by the success of the treatment but also with high interest on the impact of the treatments on patients‘ quality of life and its association with clinical progress (Basch et al., 2016). More often, the clinicians focus on the disease-related outcomes like cancer progress; however, patients have great concerns with the impact of the disease and its treatment on their daily function and life (Khan, Akhtar, & Sheikh, 2005). This understanding has increased its importance besides the traditional aim regarding disease outcomes (Carr & Higginson, 2001).

2.4.1 Health-related quality of life

The quality of life (QoL) of oral cancer survivors is equally vital to lengthen their life span (Miller & Rogers, 2018). The World Health Organization (WHO) defines QoL as *"an individual"sperception of their position in life, in the context of the culture and* *values systems in their life, and in relation to their goals, expectations, standards, and concerns"* (Nutbeam, 1998). Health-related quality of life (HRQoL) is a subset of QoL. HRQoL is the health aspect of a person's quality of life. It focuses on the impact of health on the person's level of ability, daily functioning, and capability to experience or live a fulfilling life. (Patrick et al., 2007). There are four core domains in HRQoL: (i) physical functioning; (ii) psychological functioning; (iii) social interaction, and (iv) disease and treatment-related symptoms (S. Rogers, Fisher, & Woolgar, 1999). The health aspect includes the patient's physical health, psychological state, level of independence, social relationships, personal belief, and relationship to salient features of the environment (Patrick et al., 2007). It is usually the individual's self-perceived assessment on their current health status (Karimi & Brazier, 2016), and is conducted during their follow-up clinics.

Findings from HRQoL studies could provide a better understanding of the effect of oral cancer and its related treatments on patients' life as well as the people surrounding them (Vartanian, Rogers & Kowalski, 2017). HRQoL measures can also be useful to be incorporated in the clinical practice, to improve the patient-clinician relationship, to assess the need for further treatment, rehabilitation, for symptom relief, palliative care or social support, and be used in the treatment decision-making process (Vartanian, Rogers & Kowalski, 2017). Patients' HRQoL should be continuously monitored. A recent study has shown the associative relevance of patients' HRQoL at diagnosis to predict head and neck cancer survival. It was reported that patients with better HRQoL at diagnosis have better survival compared to those who reported lower HRQoL (Rogers et al., 2020). Thus, current strategies are targeted to improve the quality of life of oral cancer survivors, especially during the post-treatment follow-up care to increase positive outcomes and minimise knowledge gaps in cancer survivorship (Aziz, 2007).

Identifying patients' HRQoL issues is central to holistic patient care. Rogers (2010) had identified issues which affect oral cancer patients' HRQoL such as carer burden and support, coping, dental status, disfigurement, emotional aspects, fear of recurrence, finance, function, information, intimacy, oral rehabilitation, PEG (per-endoscopic gastrostomy) feeding, personality, sociodemographic background, speech, swallowing, shoulder movement, trismus, and xerostomia. In a different study, PCI-H&N concerns of dental health or teeth, taste, bowel habit, fatigue or tiredness, and fear of cancer coming back were significantly associated with the social and physical domains of HRQoL of the patients' past seven days (Aguilar, Sandow, Werning, Brenneman, & Psoter, 2017).

Oral cancer patients' HRQoL outcomes are significantly associated with patient characteristics (race, gender, and age); cancer characteristics (time since diagnosis, cancer stage, and sites); and treatment-related characteristics (the extent of surgery, use of adjuvant chemotherapy or radiation therapy) (Murphy, Ridner, Wells, & Dietrich, 2007; Rogers, El-Sheikha, & Lowe, 2009; Terrell et al., 2004). The following subsections further describes oral cancer and the impact of its treatments on patients' HRQoL based on its four core domains.

2.4.1.1 Physical impact and functioning

The most common site for oral cancer is the tongue, and surgical resection is the primary treatment modality (Balasundram et al., 2012; Doss et al., 2017). Many patients presented at late stages (stage III or IV), which require more sophisticated management that can result in physical deformities and functional impairments (Kanatas et al., 2013; Scully & Bagan, 2010).

Some patients continue life as usual after completing treatments with minor adjustment; however, more often than not, oral cancer survivors often suffer profound physical impact (Balasundram et al., 2012; Good, Richard, Syrmis, Jenkins, Marsh, & Stephens, 2014; Kenneth D Miller, Pandey, Jain, & Mehta, 2015). Oral cancer patients surviving over the long term often carry an extreme physical burden in aspects of communication, ability to swallow, and facial disfigurement (Good et al., 2014). Morbidity associated with oral cancer depends on the site of oral cancers, which are, most commonly, pain in the mouth, difficulty on chewing and swallowing, speech, having problem in moving the tongue or mandible, and facial deformity (Chen et al., 2015; Terro & St J, 2017; Weatherspoon, 2017). The impact varied according to other cancer characteristics, treatment-related issues, patients‘ age, and social background, whereby less impact can be seen in younger patients, females, patients with smaller T size (between T1 – T2), posterior sites (Rathod et al., 2015). A systematic review study reported that the elderly was found to be more affected by the physical impact after 1-year of post-treatment than the younger patients with having more problems concerns on their eating, speech, fatigue, sticky saliva, mucus production, sexuality, nutritional supplements and being frail (So et al., 2012).

The Functional Assessment of Cancer Therapy (FACT) questionnaire was used in prior studies on head and neck cancer (Doss et al., 2017; Elting et al., 2008). Both studies observed a significant deterioration in patients‘ HRQoL at the early phase of post-treatment oral cancer, and subsequently almost regained to the baseline HRQoL scores at later phase of post-treatment (Doss et al., 2017; Elting et al., 2008; Molassiotis & Rogers, 2012). This outcome was expected because oral cancer and its treatments have an acute impact on patients‘ physical, personal function, and head and neck domain aspects (Doss et al., 2017). These findings are supported by a study in which it was reported that significant changes in HRQoL could be observed in a period of three to six months of continuous follow-ups and unlikely to be observed in a short period (Wiklund, Dimenäs, & Wahl, 1990).

In the latest study, it was found that hyposalivation and trismus were associated with health-related quality of life. It showed that patients who were diagnosed at advanced cancer stages and were associated with hyposalivation and trismus, had a lower quality of life that has a high impact on patients‘ daily life (Bonzanini et al., 2020). The impact has shown to mostly affect dental aspects such as chewing or eating, especially at the early phase of post-treatment (Aguilar, Sandow, Werning, Brenneman, & Psoter, 2017).

2.4.1.2 Psychological functioning

The psychosocial functioning affecting HRQoL among head and neck cancer patients varied in terms of personality, social support, satisfaction with consultation and information, behavioural factors such as consuming alcohol and smoking, and depressive symptoms (Llewellyn, McGurk, & Weinman, 2005). As suggested by Llewellyn et al. (2005), some of the factors that affect patients‘ psychosocial functioning are potentially modifiable, especially those related to informational needs that can be achieved through information sharing from supportive care groups.

Recently, it has been observed that the impact on working-age adults is higher compared to other age groups as this group has more involvement and responsibilities connected to their social, emotional, financial, and family aspects. The younger patients were more affected by emotional status concerns, and it affected their psychosocial functions ability as well (So et al., 2012). The younger patients suffer more problems with difficulty in sleeping, vomiting, nausea and financial issues (So et al., 2012). Consequently, social support is much needed to help them to overcome this issue.

Post-treatment patients‘ affected psychosocial functioning is mainly related to physical impact. Physical disfigurement could lead to life-long impact which specifically affects patients‘ appearance, especially among female patients, which had a significant impact on their psychological well-being (Parry et al., 2011). Patients with more concerns were mostly affected by the advanced oral cancer stage and required complex cancer treatment that caused more tissue destruction and needed more complex health management (Kanatas et al., 2013).

2.4.1.3 Social interaction

Social interaction involves communication between patients and other people. Most patients with low HRQoL were among the younger age group patients (So et al., 2012) (Doss et al., 2017b), as socialising scored highly in their routine life, especially among those who are still working. The physical impairment disrupts a patient‘s daily life (mainly speech, eating ability, swallowing) and social functions (such as communication and interaction aspect) (Molassiotis & Rogers, 2012). Patients on PEG tubes would be more affected by social interaction and would avoid public appearance (So et al., 2012). The patients would have difficulties pronouncing words, communication and interaction are interrupted; and thus, cause a breakdown in the communication process. Additionally, post-treatment oral cancer patients would also avoid social interaction as the physical disfigurement has the potential of causing low self-esteem to interact with other people, and they are in the phase of adapting and coping with the changes as cancer survivors (Dunne et al., 2017; Ganzer, Rothpletz-Puglia, Byham-Gray, Murphy, & Touger-Decker, 2015). As such, post-treatment patients are prone to minimise their public appearance in their daily activities and socialising such as attending functions in either work-related or non-work-related capacity. Besides that, since permanent physical impact (e.g. tongue or lip dissection) caused difficulty in speech (Molassiotis & Rogers, 2012), it affects their pronunciation, and thus caused difficulty among others to understand them.

2.4.1.4 Disease and treatment-related symptoms

Patients‘ HRQoL is mainly related to their oral cancers and the treatments they received (Rogers et al., 1999). The level of their HRQoL also indirectly affects their carers, and others who care for them (Rogers, 2010; Terrell et al., 2004); thus, the consequence is encompassing. As mentioned before, oral cancer patients are mostly diagnosed at late cancer stages. The late staging increases the complexity of their treatment and management, and thus caused a higher impact on patients‘ HRQoL (Balasundram et al., 2012). The choice of treatment provided to the patients depended not only on patients‘ clinical characteristics, but also the impact of the after-treatment effect on patients‘ HRQoL and survival probabilities (Cheng et al., 2017; Terrell et al., 2004). A study conducted among post-treatment head and neck cancer patients had reported that a few clinical characteristics were significant for the decrement in patients‘ quality of life, namely medical co-morbid conditions, the presence of a tracheotomy tube, chemotherapy, and neck dissection. Among all these predictors of HRQoL, an earlier study found that the presence of PEQ tube and co-morbid conditions had shown to be strong predictors of HRQoL (Terrell et al., 2004).

In general, oral cancer treatments include surgery, radiotherapy, chemotherapy, or a combination of these treatment modes. However, these treatments often lead to undesirable impact, which mostly affects the patients‘ physical and psychosocial aspects (So et al., 2012). The different procedure of treatment modalities produced different treatment side effects. The effects from the procedures such as tongue dissection could cause loss of sensation and neuropathic pain, or the removal of the mandible may leave patients with difficulties in mastication and speech, and involving facial aesthetics which caused disfigurement. All these effects have a negative impact on patients‘ quality of life.

Meanwhile, many patients who underwent radiotherapy experienced effects on their skin, subcutaneous tissue, mucous membrane, xerostomia, and difficulty in swallowing (Langendijk et al., 2008), which impact patients‘ emotional and social functioning. In the study, it was observed that difficulty in swallowing had a higher impact on HRQoL than xerostomia in the first 18 months of post-radiotherapy (Langendijk et al., 2008). In terms of HRQoL domain, radiation therapy was associated with worse physical and functional well-being domain compared to other domains (Reeve et al., 2016).

2.4.2 Psychological distress

The National Comprehensive Cancer Network (NCCN) defines distress as *“multifactorial, unpleasant experience of an emotional, psychological, social or spiritual nature that interferes with the ability to cope with cancer, its physical symptoms, and its treatment. Distress extends along a continuum ranging from normal feelings of vulnerability, sadness, and fear to disabling conditions such as clinical depression, anxiety, panic, isolation and existential or spiritual crisis”* (Riba et al., 2019). Psychological distress is also related to various other factors, mainly pain, prognosis aspect, alcohol and tobacco risk habits, alteration to body image, history of psychiatric illness, treatment, pre-morbid factors and social stresses (Shapiro & Kornfeld, 1987). The detection of distress and its management in oral cancer patients is an essential aspect of clinical care which was found significantly related to patients‘ outcomes (Ryan et al., 2005). This paradigm shift is vital as the identification and treatment of psychosocial issues are now considered an essential standard of patient care.

Thus, the inability to detect patients‘ psychological state of health can impose negative impacts to their routine life (KEnDAll, Hamann, & Clayton, 2012) which affected mostly due to their physical impairment and further imposes on their overall well-being (Ryan et al., 2005). Studies had shown that 25-50% of cancer patients might have negative outcomes such as increased suffering, reduced quality of life for the patients and family, reduced progression to the treatment and possibility of decreased survival odds (KEnDAll et al., 2012). There may also be psychosocial sequelae that can adversely affect the patient‘s quality of life (Cherith Semple et al., 2013).

Psychological distress is higher among head and neck cancer patients compared to other types of cancers (Frampton, 2001). Whilst in comparison to cancer patients in general, head and neck cancer patients are amongst the most distressed (Carlson et al., 2004) mainly due to problems related to basic daily function of speech and swallowing (Verdonck de Leeuw et al., 2007). In the worst situation, head and neck cancer survivors are subject to increased suicidal risk. A population-based analysis of Surveillance, Epidemiology and End Results (SEER) reported that suicide rate among head and neck cancer survivors was significantly higher compared to the general US population, and the males were six times more likely to commit suicide than females (Osazuwa-Peters, Arnold, Loux, Varvares, & Schootman, 2018).

Patients who are at risk of psychological distress were also associated with lower quality of life and had difficulties in performing daily functions (Shiraz, Rahtz, Bhui, Hutchison, & Korszun, 2014). An increase of psychological distress levels among post-treatment oral cancer patients was also associated with eating problems, fear of recurrence, fatigue, distress, anxiety and depression (Wells et al., 2015). The prevalence of depression and psychological distress did not differ greatly by tumour stage.1 However, the slightly greater risk increase among patients with locally advanced cancer beyond 1 year after diagnosis might indicate a direct effect of the disease course, treatment adverse effects, and disease coping after the primary cancer treatment (ACTION Study Group, 2017; Lu et al., 2016). Another study had found that younger patients who had been inserted with a feeding tube (PEG tube), having other comorbidities, staying alone and unemployed were associated with higher levels of distress (Wells et al., 2015). Significantly, one study reported that higher incidence of psychological distress was among younger age patients of oral cancer who had undergone a maxillectomy procedure and had recurrent episodes of cancer (Wang, Qin, Li, Li, & Lu, 2018). Higher impact of psychological distress was also reported among the younger age patients than the older patients age above 65 years old (Chiou et al., 2016; Wells et al., 2015). This could be possibly due to younger patients starting to build their life pathway in term of career and relationship compared to the older cohort group which could have already accomplish a stable life (Admiraal, van Nuenen, Burgerhof, Reyners, & Hoekstra, Weebers, 2016).

However, their study did not reveal a positive psychological change with the ‗time after treatment completed' (Harding & Moss, 2018). Post-treatment oral cancer patients may experience prolonged psychological distress even after five years of treatment (Pocobelli et al., 2019). Patients' HRQoL showed a linear relationship with psychological distress level whereby as patients' HRQoL improved, the lower the risk of patients' having psychological distress. This showed that psychological distress is as equally important as HRQoL in achieving positive post-treatment outcomes which require an early detection through screening of patients' psychological distress during routine follow-up consultation. Besides that, post-treatment oral cancer patients should learn on coping skills from the diagnosed phase in preparing the patients to deal with the debilitating effect from psychological distress such as ‗patient burnout' (Morris, Moghaddam, Tickle, & Biswas, 2018). Oral cancer patients experience psychological distress even at pre-diagnosis phase as an impact from the oral cancer symptoms, during the diagnosis as due from the investigation and treatment planning and further at post-treatment phase as due to the effect after treatment, recovering and coping to new norm after cancer treatment (Lu et al., 2016).

Post-treatment oral cancer patients are at risk of mental health issues such as fear of recurrence, distress, anxiety and depression as a subsequent long impact from oral cancer and its treatment (Lu et al., 2016). In a study conducted among cancer patients, post-treatment oral cancer patients are at risk of mental disorders before being diagnosed, which spiked during the first week after diagnosis, decreased immediately after that and then remained plateau for ten years after diagnosis (Lu et al., 2016). As such, it compromised and disrupted the patients‘ lifestyles, daily activities and their interests (Devins & Deckert, 2018).

A few screening instruments for anxiety and depression in cancer patients had been used in many studies and categorised as (i) ultrashort (1-4 items); (ii) short (5-20 items); and (iii) long (21-50 items) (Vodermaier, Linden, & Siu, 2009). The most frequently used among head and neck cancer patients were Hospital Anxiety and Depression Scale (HADS) (Zigmond & Snaith, 1983), Distress Thermometer (DT) (Roth et al., 1998), Depression, Anxiety Stress Scale (DASS) (Lovibond, 1983), and Beck Depression Inventory (BDI) (Beck, Rial, & Rickels, 1974). The present study had used DT to measure patients‘ psychological distress level as it is a simple tool and the problem items are almost similar to PCI-H&N specific items. This instrument is recommended by NCCN to be routinely used during the follow-up sessions as a validated screening tool (National Comprehensive Cancer Network, 2003; Riba et al., 2019).

The DT was first introduced in 1998 by Roth et al. and has been validated for Malaysian use (Yong, Zubaidah, Saidi, & Zailina, 2012). A Distress Thermometer (DT) questionnaire was used in an earlier study to address patients‘ unmet psychosocial needs and revealed that the most issues contributing to risk of distress were financial, worry, nervousness, getting around, and sleep (VanHoose et al., 2015). Those who were at risk for high psychological distress level were 5.57 times more likely to endorse problems related to worry (VanHoose et al., 2015). For clinical practice in Malaysia, DT level of four and above suggested that the patient has signs of distress and need to be referred to a psychologist for further management (Yong et al., 2012). As psychological distress has shown its relevance and importance to be used routinely in everyday clinical practice, another study was conducted to determine its relationship with a prompt list that is routinely used during post-treatment oral cancer follow-up clinics (Ghazali, Roe, Lowe, Tandon, Jones, Shaw, et al., 2017). In that study, a significant cut-off point of four or five of patients‘ selected items that they wished to discuss with their clinicians, could indicate that patients are at risk of distress without using the DT questionnaire. PCI domains significantly related to distress were emotional status issues and physical function (Ghazali, Roe, Lowe, Tandon, Jones, Shaw, et al., 2017).

2.4.3 Satisfaction with follow-up consultation

Patients‘ satisfaction has been an interest in health care as part of patients‘ outcome indicator (Petrosyan, Patel, & Ameerally, 2017). Patients‘ satisfaction has also been monitored as a quality measurement in provision of health care services in order to meet patients‘ needs and current demands while assessing the availability of their resources in fulfilling increasing demand in health management (Al-Abri & Al-Balushi, 2014; Faezipour & Ferreira, 2013). Thus, the self-reported measurement of patients‘

satisfaction included items based on the providers‘ care and patients‘ expectations (Ware Jr, Snyder, Wright, & Davies, 1983). Post-treatment patients‘ satisfaction levels, on the other hand, are often dependent on their improved sense of well-being and reduced psychological distress (Llewellyn, Horne, McGurk, & Weinman, 2006).

Many available questionnaires have been developed to measure patients‘ satisfaction, such as satisfaction with cancer information profile (SCIP) (Llewellyn et al., 2006), during initial oncology consultation (Brown, Hill, Burant, & Siminoff, 2009), doctor-patient communication questionnaire (DPC) (Sustersic et al., 2018), and physician-patient relationship (PPRI) (Zachariae et al., 2001), used as a routine assessment in daily clinical practice.

There are barriers to providing the best health care to meet patients‘ expectations. In a study conducted by Brandes, Linn, Smit, and van Weert (2015) among oral cancer patients survivors, the most significant barriers depended on the location and surrounding where the consultation takes place (e.g., perceived lack of time), and related to the providers‘ behaviour (e.g., providers do not encourage patients to express and share their concerns).

Patients‘ satisfaction is used in various phases of health care services either at primary care (Hojat et al., 2011), initial diagnosis (Byrne & Rogers, 2017), during treatment (Kim et al., 2020; van Weert et al., 2009), post-treatment (Petrosyan et al., 2017), and among the survivors. Majority of the available questionnaires concentrated on achieving effective patient-clinician communication, tailored communication, unmet needs, shared decision making, satisfaction with the timing and involvement of the multidisciplinary team in managing the patients (Brandes et al., 2015; Gasquet et al., 2004; Hojat et al., 2011; Jean, Pierre et al., 2011; Llewellyn et al., 2006; van Weert et al., 2009) of which all were initiated by the clinicians. As such, the health providers could assist patients in improving their communication skills by utilising the questions‘ prompt that can be most beneficial to improve patients‘ knowledge and helps patients to recall previous related events (Coulter & Ellins, 2006). Although the study by Coulter and Ellins (2006) reported that patients were more involved in the shared decision making, however, there was no significant effect on patients‘ satisfaction, mood or treatment outcomes.

Many studies had associated patients‘ satisfaction in achieving a patient-centred care concept (Nielsen, Mehlsen, Jensen, & Zachariae, 2017; Rathert, Wyrwich, & Boren, 2013). The health provider can assess that the patient-centred care approach had achieved its objective when patients showed high levels of satisfaction related to lower levels of psychological distress (Nielsen et al., 2017). Patient-clinician communication is a crucial aspect in achieving patients‘ satisfaction with the information delivered and failure to do so could contribute to post-consultation distress (Nielsen et al., 2017).

2.5 Post-treatment oral cancer patients’ concerns

Issues of patients‘ concerns vary between individuals. Some may have similar individual and cancer characteristic profiles but possess different issues or concerns regardless of their differences in the cultural background (Rogers et al., 2019). The impact from oral cancer treatment varies according to the cancer sites, staging, treatment modalities, patient‘s age and time since after treatment completed (Kanatas et al., 2013; Razak, Saddki, Naing, & Abdullah, 2010). The numbers of PCI items were strongly associated with the overall patients‘ quality of life (QoL) (Rogers et al., 2019).

Patients tend to raise more issues to be discussed with their clinicians when they have high or more unmet needs (Ringash et al., 2018) that are highly related to patients‘

physical status, personal function and emotional status (Hatta, Doss, & Rogers, 2014). In terms of age, younger patients were observed to have more concerns than older patients. More responsibility on family commitment, career development, the interest of personal activities and social obligations among the younger age population compared to the elderly (Katz, Peace, & Spurr, 2011; Verdonck-de Leeuw, van Bleek, Leemans, & de Bree, 2010) can lead to unmet needs. As time after oral cancer treatment completed progresses, patients will learn to adapt to the new changes either from the outcome of the cancer or the treatment they received. This is mainly because they learnt to adapt and adjust their routine chores to maintain social interaction for the new future (Ganzer et al., 2015). Part of the social interaction is the ability to perform their routine life (e.g. working) as before being diagnosed with oral cancer. A study conducted by Verdonck-de Leeuw et al. (2010) showed that some survivors (n=71%) managed to resume their life like before treatment by returning to work within six months post-treatment.

Advanced head and neck cancer treatment not only needs complex patient management but also can lead to lifelong detrimental impacts to patients‘ life and high morbidity (Balasundram et al., 2012; Weatherspoon, 2017). This prolonged morbidity leads to high numbers of concerns among post-treatment oral cancer patients. As such, post-treatment patients have more concerns at the early phase after completing treatment as they are going through a difficult time in their life recovering and adapting to new norms (Fletcher, Cohen, Schumacher, & Lydiatt, 2012; Ganzer et al., 2015; Shunmugasundaram, Rutherford, Butow, Sundaresan, & Dhillon, 2019). As time progresses, patients learn to adapt to their new situation by accepting and coping with the challenges to maintain social interaction and resume life as before diagnosed (Ganzer et al., 2015; Verdonck-de Leeuw et al., 2010).

Most studies showed that the concern of ‗fear of recurrence‘ concern was commonly reported among oral cancer survivors (Rogers et al., 2019). In a previous local study, it was observed that issues from physical status (94.4%), specifically on chewing (48.6%), were frequently selected (Hatta, Doss & Rogers, 2014). In another study, ‗fear of recurrence‘ was strongly predicted by optimism and pre-treatment fears which showed the importance of reassurance before treatment and at follow-up visits (Llewellyn, Weinman, McGurk, & Humphris, 2008). Findings among mixed cancer survivors in Singapore had demonstrated that ‗fear of cancer recurrence‘ was slightly more than four times than that reported in Western populations (32.1% vs 7%), and was significantly associated with younger patients, higher educational level and higher levels of emotional distress (Mahendran et al., 2020).

Besides ‗fear of recurrence‘, other common issues raised at the early stage of post-treatment oral cancer treatment were on dental health/teeth, taste, salivation, chewing, swallowing, mouth opening, fatigue, sleeping, speech, and pain (Rogers & Barber, 2017). Whereas, long term oral cancer survivors often present with delayed dysfunction resulting from previous cancer treatment. These effects include xerostomia, dental decay, pathological fractures, soft tissue fibrosis, osteoradionecrosis, which often arose many months or years after treatment completed with dysphagia and chewing difficulties remaining as a persistent effect in the late effects stage (Hutcheson et al., 2012; Taibi et al., 2014).

Long-term impacts and the complexity of the oral cancer treatment (such as chemotherapy and radiotherapy) could cause the adverse effect of saliva stickiness, dryness in their mouth, dysfunctional eating, sensory disorders and speech problems, which affected patients‘ HRQoL (Bower, Vlantis, Chung, & Van Hasselt, 2010; Doss et al., 2017).

Some issues such as sexuality/intimacy or lifestyles habits (smoking/alcohol) were not selected by the patients as they tended to be more reserved and felt inappropriate to discuss the matter openly with the clinicians (Rogers et al., 2009; Rogers, Hazeldine, O‘Brien, Lowe, & Roe, 2015), and it could also be the clinicians were not addressing this issue on intimacy in relationship (Hautamäki, Miettinen, Kellokumpu-Lehtinen, Aalto, & Lehto, 2007; Ussher et al., 2013). In a recent study, patients preferred to discuss sexuality issues ‗at the time of diagnosis', and only half of the study participants (n=35/70) preferred to discuss it with the health personnel (Rhoten, Davis, Baraff, Holler, & Dietrich, 2020).

2.6 Availability of quality indicator measurement for oral cancer patients

Continuous improvements in managing oral cancer survivors have always been discussed and revised (NCCN, 2019). These discussions and revisions suggested increasing positive outcomes among oral cancer survivors and to minimise gaps in knowledge and research areas in cancer survivorship (Aziz, 2007). In recent years, patient-reported outcome measures (PROMs) (Rogers & Barber, 2017) and question prompt lists (QPLs) (Miller & Rogers, 2018) have been of increasing interest to clinicians. These instruments are conducted through patients‘ self-assessment. The premise is that the patients' experiences and concerns can be used as indicators of their overall well-being and coping ability with their disease and treatment received (Foster, Croot, Brazier, Harris, & O‘Cathain, 2018). However, patients revealed that there are a few issues not addressed by self-report surveys, particularly issues on (i) elicitation of relevant information, (ii) symptom burden issues, (iii) psychological issues, and (iv) physical barriers (Rhoten et al., 2020).

These instruments are intended to maximise overall patients outcomes at any phase of cancer management (Rogers & Barber, 2017; Sansoni, Grootemaat, Duncan, Samsa, & Eagar, 2014), evaluate patients' satisfaction, improve patient-clinician communication, and encourage shared decision making during a consultation (Chen, Ou, & Hollis, 2013).

2.6.1 Patient-reported outcomes measured (PROMs)

PROMs are an approach to measure and assess patients‗ outcomes which have been reported to benefit patients and the clinicians for better quality health management. The findings from PROMs could assist clinicians to make decisions in their patient management at any phase of the process either before or after being diagnosed, during treatment, post-treatment or throughout survivorship (Rogers & Barber, 2017). It is available according to the patient‗s experience at different phases of management (Rogers & Barber, 2017). In their study, the PROM used was an assessment of the patient‗s experience after clinical treatment has completed, which create a detrimental impact on their HRQoL.

Routine use of PROMs has been shown to establish and monitor patients‗ outcomes especially on their quality of life (QoL) and psychological aspects (Doss et al., 2017; Ghazali et al., 2015; Ghazali et al., 2017). The use of PROMs at an individual patient level supports patient-centred care (Foster et al., 2018). The patient-clinician communication improved among those who used PROMS routinely in the clinic (Velikova et al., 2004).

However, it was not routinely practised in clinical management as it was reported to have perceived barriers (Antunes, Harding, Higginson, & EUROIMPACT, 2014; Rogers, 2009). The barriers were mainly due to the time-consuming aspect, limited resources to distribute the PROMs, an additional process to the routine practise, limited evidence that the implementation adds value to the clinical management of the patient, and lack of understanding of the questionnaires used which can have a high impact on the quality of data collected (Antunes et al., 2014; Rogers, 2009). In addition, Nguyen et al. (2020) reported that the perceived barriers were also contributed by low workplace awareness on PROMs use, unavailability of PROMs in patients' preferred language and non-integrated PROMs in the electronic patients' record system.

Rogers and Barber (2017) had concluded the six main categories of PROMs were: ~~1~~) those addressing issues not specific to cancer; 2) those addressing issues common to all cancers; 3) questionnaires with items specific to HNC; 4) questionnaires that focus on a particular aspect of head and neck function; 5) those measuring psychological concerns, such as depression, anxiety, or self-esteem; and 6) item prompt lists."

Most frequently, the PROMs used with head and neck cancer patients are as shown in Table 2.2. Shunmugasundaram et al. (2019) has conducted a systematic review on PROMs on patients' unmet need among oral cancer patients. The study had developed a conceptual framework on the aspects that should be in a PROMs for unmet needs. The 12 unmet needs of crucial issues in head and neck cancer patients are: 1) physical needs; 2) psychological needs; 3) information needs; 4) activities of daily living; 5) social needs; 6) spiritual/ existential needs; 7) nutritional needs; 8) dental needs; 9) communication needs; 10) sexual needs; 11) financial needs; and 12) access to care (Shunmugasundaram et al., 2019).

To date, the tool to measure or assess patients' unmet needs specifically for head and neck cancer patients is PCI-H&N (Rogers et al., 2009). Other available measurement tools on unmet needs did not cover dental needs component (Shunmugasundaram et al., 2019) such as Cancer Needs Questionnaire – Short Form (CNQ-SF) (Foot & Sanson-Fisher, 1995), Supportive Care Needs Survey – Short form

34(SCNS-SF 34) (Boyes, Girgis, & Lecathelinais, 2009), Survivors Unmet Needs Survey (SUNS) (Sanson, Fisher et al., 2000), Cancer Survivors‘ Unmet Needs Measure (CaSUN) (Hodgkinson et al., 2007), and Cancer Patient Need Survey (CPNS) (Wingate & Lackey, 1989). As to date, most of the tools available to measure patients‘ unmet needs do not cater to specific disease which involves dental and nutritional needs. These specific needs are substantial among oral cancer patients as they are mostly affected due to cancer‘s impact on their dental and eating functions. If these needs are neglected, it could lead to negative outcomes (Shunmugasundaram et al., 2019). Currently, no instrument addresses dental needs except the PCI for head and neck cancer (Rogers et al., 2009; Shunmugasundaram et al., 2019).

Patient-reported outcome measures (PROMs) has attracted the attention of clinicians as patients' experience and concerns may be the best indicator to assess patients' overall progress on the disease and treatment provided (Foster, Croot, Brazier, Harris, & O‘Cathain, 2018). There were many available PROMs with a similar purpose to maximise overall patients‘ outcomes at any phase of the cancer management (Rogers & Barber, 2017). PROMs can be used to evaluate patients' satisfaction, improving patient-clinician communication, and shared decision making between the patients and clinicians (Chen, Ou, & Hollis, 2013).

2.6.2 Question prompt list

Questions Prompt List is a communication aid consisting of a structured list of questions to facilitate patients in participating during the consultation sessions by encouraging question-asking (Clayton et al., 2003). The effectiveness of patient-clinician communication has shown to produce positive patients‘ outcomes (Rao, Anderson, Inui, & Frankel, 2007) by promoting patient empowerment during consultation sessions. The questions are related to various relevant aspects of a cancer diagnosis. Similarly to PROMs, QPL is given to patients before a consultation session

(Clayton et al., 2003). The discussion during consultation session is guided by the patients‘ questions asked and prompted a shared decision making by sharing their concerns (Brown et al., 2011; Clayton et al., 2003). Question prompts would be able to provide patients with the knowledge, and importantly it could help in information recall to minimise the knowledge gap between researcher, clinicians and patients (Coulter & Ellins, 2006).

Although QPL and PROMs are almost similar in many ways, both are different in terms of specific items/statements about the cancer types. PROMs are more specific tools, whereas QPL consists of general questions that are common in other types of cancer (Miller & Rogers, 2018).

Table 2.2: Most commonly used PROMs relevant to head and neck cancer patients assessing patients‘ unmet needs. (Adopted from source: Miller & Rogers, 2018; Shunmugasundaram et al., 2019).

PROMs	**Reference**	**Title**	**Description**
Cancer Patient Needs Survey (CPNS)	(Wingate & Lackey, 1989)	A description of the needs of noninstitutionalized cancer patients and their primary care givers. Cancer nursing.	• 51-item assessing unmet needs among terminal cancer patients • covers 42% of content relevant to HNC
Cancer Rehabilitation Evaluation System (CARES)	(Schag & Heinrich, 1990)	Cancer Rehabilitation Evaluation System (CARES).	• 139 items assessing unmet needs among mixed cancer groups excluding head and neck cancer patients. • Covers 75% of content relevant to HNC
Cancer Rehabilitation Evaluation System-Short form (CARES-SF)	(Schag, Ganz, & Heinrich, 1991)	CAncer rehabilitation evaluation system–short form (CARES- SF). A cancer specific rehabilitation and quality of life instrument	• 59 items assessing unmet needs among breast cancer patinets • Covers 75% of content relevant to HNC

Table 2.2: Most commonly used measurement tools relevant to head and neck cancer patients assessing patients' unmet needs. (Adopted from source: Miller & Rogers, 2018; Shunmugasundaram et al., 2019) (continued)

PROMs	**Reference**	**Title**	**Description**
Question Prompt List (QPL)	(Butow, Dunn, Tattersall, & Jones, 1994)	Patient participation in the cancer consultation: Evaluation of a question prompt sheet	• QPL is a structured list of patients asking questions to the clinicians. It support addressing patients concerns and facilitate patient-clinician communication • the variation of numbers of questions developed for specific disease are very wide, ranging from 11 to 189 questions.
Cancer Needs Questionnaire- Short Form (CNQ-SF)	(Foot & Sanson-Fisher, 1995)	Measuring the unmet needs of people living with cancer. Paper presented at the Cancer Forum.	-contains 32-item assessing needs of mixed cohort cancer patients including head and neck cancer patients. -covers 50% of content relevant to HNC
Cancer Needs Questionnaire- Short Form (CNQ-SF)	(Foot & Sanson-Fisher, 1995)	Measuring the unmet needs of people living with cancer. Paper presented at the Cancer Forum.	-contains 32-item assessing needs of mixed cohort cancer patients including head and neck cancer patients. -covers 50% of content relevant to HNC

Table 2.2: Most commonly used measurement tools relevant to head and neck cancer patients assessing patients‘ unmet needs. (Adopted from source: (N. Miller & Rogers, 2018; Shunmugasundaram et al., 2019) (continued)

PROMs	**Reference**	**Title**	**Description**
Survivors Unmet Needs Survey (SUNS)	(Sanson- Fisher et al., 2000)	The unmet supportive care needs of patients with cancer.	89-item assessing unmet needs among post-treatment cancer survivors and one to five years post-diagnosis excluding head and neck cancer patients • Covers 58% of content relevant to HNC
Needs Evaluation Questionnaire (NEQ)	(Tamburini et al., 2000)	Assessment of hospitalised cancer patients' needs by the Needs Evaluation Questionnaire.	• 23 items assessing unmet needs among hospitalised cancer patients excluding head and neck cancer patients • covers 75% of content relevant to HNC
Psychosocial Needs Inventory (PNI)	(Thomas et al., 2001)	The psychosocial needs of cancer patients and their main carers	• 48 items assessing psychosocial unmet needs among patients and their carers excluding H&N cancer patients. • Covers 83% of content relevant to HNC

Table 2.2: Most commonly used measurement tools relevant to head and neck cancer patients assessing patients' unmet needs. (Adopted from source: (N. Miller & Rogers, 2018; Shunmugasundaram et al., 2019) (continued)

PROMs	**Reference**	**Title**	**Description**
Assessment for Advanced Cancer Patients (NA-ACP)	(Rainbird, Perkins, & Sanson- Fisher, 2005)	The Needs Assessment for Advanced Cancer Patients (NA- ACP): a measure of the perceived needs of patients with advanced, incurable cancer. A study of validity, reliability and acceptability	• 132-item assessing unmet needs among advanced cancer patients in a mixed cohort cancer groups including head and neck • NA-ACP covered 83% of content relevant to HNC, but has no items representing sexual and dental needs.
Problem and Needs in Palliative Care Questionnaire (PNPC)	(Richardson, Medina, Brown, & Sitzia, 2007)	Patients' needs assessment in cancer care: a review of assessment tools.	• 138 items assessing patients problems and needs in palliative care including H&N cancer patients • Covers 67% of content relevant to HNC
Cancer Survivors' Unmet Needs Measure (CaSUN)	(Hodgkinson et al., 2007)	The development and evaluation of a measure to assess cancer survivors' unmet supportive care needs: the CaSUN (Cancer Survivors' Unmet Needs measure)	• 35-item assessing general cancer survivors excluding head and neck cancer patients. covers 75% of content relevant to HNC

Table 2.2: Most commonly used measurement tools relevant to head and neck cancer patients assessing patients‘ unmet needs. (Adopted from source: (N. Miller & Rogers, 2018; Shunmugasundaram et al., 2019) (continued)

PROMs	**Reference**	**Title**	**Description**
Supportive Needs Screening Tool (SNST)	(Pigott, Pollard, Thomson, & Aranda, 2009)	Unmet needs in cancer patients: development of a supportive needs screening tool (SNST).	• 40 items unmet needs to screen for supportive needs among cancer patients excluding HNC • covers 67% of content relevant to HNC
Supportive Care Needs Survey- Short Form 34 (SCNS-SF 34)	(Boyes et al., 2009)	Brief assessment of adult cancer patients' perceived needs: development and validation of the 34- item Supportive Care Needs Survey (SCNS- SF34).	-contains 34 items assessing needs of mixed cohort cancer patients excluding head and neck cancer patients -cover 67% of content of content relevant to HNC
Patient Concerns Inventory (PCI)	(Rogers et al., 2009)	The development of a Patients Concerns Inventory (PCI) to help reveal patients concerns in the head and neck clinic.	• Self-reported prompt list consist of 57 specific patients‘ concerns to be discuss with clinician during their follow-up consultations. • Specifically for the use in head and neck region which cover all HRQoL aspect and dental needs. • Covers 100% content relevant to head and neck cancer patients

Table 2.2: Most commonly used measurement tools relevant to head and neck cancer patients assessing patients‘ unmet needs. (Adopted from source: (N. Miller & Rogers, 2018; Shunmugasundaram et al., 2019) (continued)

PROMs	**Reference**	**Title**	**Description**
James Supportive Care Screening (JSCS)	(Wells- Di Gregorio et al., 2013)	Management at a Comprehensive Cancer Center.	• JSCS covered 83% of content relevant to HNC, failing to include items for activities of daily living and dental needs.

2.7 Patient Concerns Inventory of Head and Neck (PCI-H&N): The new procedure during post-treatment oral cancer follow-ups in addressing patients concerns.

Oral cancer survivors require total patient care not only for symptoms relief but in managing their survival concerns, functional capacity and needs. More strategies have been targeted to better improve the state of the oral cancer survivors, especially during the post-treatment follow-up care to increase positive outcomes among oral cancer survivors and minimise the gaps in knowledge and research areas in cancer survivorship (Aziz, 2007). Many studies had been conducted in improving patient-clinician communication, patients‘ engagement in shared decision making, patients‘ psychological distress, satisfaction, and in patient‘s quality of life. These studies used interventions or improvement in their procedures to identify patients‘ concerns and needs, and state of psychological level (Berger et al., 2019; Ho et al., 2011; Rogers et al., 2009). Some of the interventions used among oral cancer survivors were Question Prompt List (QPL) (Clayton et al., 2003), Post-traumatic Growth Inventory (PTGI) (Tedeschi & Calhoun, 1996), and Patient Concerns Inventory (PCI) (Rogers et al., 2009). Generally, the intervention is an inventory list comprising of items related to patients‘ disease outcomes and health-related quality of life items that promote patients‘ involvement in shared decision making and improve patient-clinician communication.

Rogers et al. (2009) had initiated a Patient Concerns Inventory for head and neck which allows patients to highlight the listed items specific to head and neck cancer patients, which are specific to their concerns, needs and priorities (Rogers et al., 2009). It consists of post-treatment patients‘ specific concerns grouped in a structured HRQoL domains that can be used as a structured guide during patient consultations (Ghazali et al., 2015). Since PCI was introduced in 2009, it had gone through a series of improvement from 45 items and eight multidisciplinary teams (MDT) in 2009 to 55 items and 15 MDT in 2013, and the latest in 2015 with 57 items (one free text) and 18 MDT (Rogers et al., 2009; Ghazali et al., 2015). The five domains are physical and functional well-being, social care and well-being, psychological and emotional well-being/spirituality, treatment-related and others (Ghazali et al., 2015). The groupings have the advantage to ease self-completion by patients, guide discussion session and identify if the patients need referrals to other units (Cancer Action Team, 2007).

PCI-H&N is an adjunct to conceptualise the initiation to improve patient-clinician communication, better patient-centred care and encourage the multidisciplinary team approach. This tool could gain better patients‗ satisfaction with the follow-up consultation, uncovering patient‗ unmet needs through the shared decision making and further improve on their clinical outcomes (Rogers & Barber, 2017). Since PCI-H&N has the potential to identify patients‗ concerns and needs to be discussed with the clinicians or consultants during the follow-up clinics, the clinicians can focus on the targeted, individualised issues during the discussion session without compromising the quality of care towards patients (Ghazali et al., 2013). Thus, the time taken for consultation is optimised and the time was not prolonged with many issues raised (median eight minutes with PCI-H&N, seven minute without PCI-H&N) (Rogers et al., 2009). Identifying individual concerns allowed patients to be referred to other multidisciplinary members for further holistic patient management (Rogers et al., 2009). PCI-H&N also prompted patients to be involved in the discussion which engaged patients in the shared decision making. It is also an aid for patients who have verbal communication problems due to post-treatment effects, which limit their communication or speech during the consultation (Ghazali et al., 2013).

PCI functions as a patient-reported outcome measure (as an item-specific prompt list) (Rogers & Barber, 2017), and as a communication tool to encourage question asking (as a QPL) (Miller & Rogers, 2018). PCI-H&N consists of a set of structured HRQoL issues that act as a guide during patient-clinician consultation and promotes multidisciplinary care (Ghazali et al., 2015). This prompt list provides an opportunity for oral cancer patients to effectively communicate with their clinician and also offers an insight of patients‘ concerns or worries which can assist clinicians better to manage their patients and family members (Foster et al., 2018). However, environmental factors can also restrict effective patient-clinician communication and can lead to barriers in addressing patients' unmet needs. The pandemic outbreak of coronavirus disease 2019 (COVID-19), for example, has created a need for new norms of patient approach as the usual face-to-face consultation between patient-clinician at clinics is currently being kept to a minimum. Guided by prompt lists, clinicians are able to discuss their patients' concerns through structured telephone consultations (Anastasios Kanatas & Rogers, 2020; Kanatas & Rogers, 2020) as a suitable alternative to ensure the continuity of holistic patient care.

PCI for head and neck cancer can detect the impact on oral cancer patients‘ QoL by validating it with HRQOL questionnaires. It can also perform as a screening tool in the follow-up of head and neck cancer patients (Rogers, Lowe & Kanatas, 2016). Screening and support should be provided as early as possible to optimise care, improve satisfaction and enable needs to be met (Rogers, Lowe & Kanatas, 2016). Patients are allowed to select issues of their concerns more than once. The study conducted by Vartanian et al. (2017) found that there is a link between the type and number of items raised on PCI and QoL (Vartanian, Rogers & Kowalski, 2017).

Issues of limited resources in the healthcare system is not new and thus, PCI could enhance patients‘ management by the most appropriate personnel and also hence overcome limited resources while promoting MDTs (Rogers et al., 2009). PCI is a specific inventory that is already widely used in different areas such as breast cancer, rheumatology and others (Ahmed et al., 2016; Kanatas et al., 2013). PCI for head and neck cancer was first introduced in the form of computer-assisted technology using touch screen (TST) version (Rogers et al., 2009).

In Malaysia, PCI-H&N (Rogers et al., 2009) had been translated and cross-culturally adapted in 2014 (Hatta, Doss & Rogers, 2014). The study used the paper version of PCI-H&N which consisted of 43 items grouped into seven domains: physical status, emotional status, personal function, social or family relationship, economic status, diet-related issues, and others (Hatta, Doss & Rogers, 2014). Hatta, Doss & Rogers (2014) had made few changes from the original PCI-H&N, Rogers et al. (2009): 1) the merging of concerns (‗sex & ‗intimacy‘; ‗energy levels & ‗fatigue‘) as single issues; 2) additional new concerns of ‗health supplement‘ & ‗diet restrictions‘; 3) removal of two concerns of ‗mood‘ and ‗temperament and personality‘; 4) inserted a check-box format; and 5) grouped the concerns into seven domains.

As for the present study, the PCI-H&N used was an adaption, which is a combination of the latest version from Ghazali, Roe, Lowe, and Rogers (2015) and Hatta, Doss & Rogers (2014). This adapted list consisted of 52 specific concerns grouped into seven main domains of physical status, emotional status, personal function, social or family relationship, economic status, diet-related issues, and others. It consisted of an additional nine items from Ghazali et al. (2015): ‗breathing‘, ‗coughing‘, ‗carers‘, ‗dependant/children‘, ‗home care/ district nurse‘, ‗coping‘, ‗self-esteem‘, ‗fear of adverse events‘, and ‗mood). The differences of patients‘ concerns in comparison to the latest PCI-H&N (Ghazali et al., 2015) is as shown at Table 2.3. The present study utilised two versions of the PCI-H&N, namely paper and a computerised web-based version.

Table 2.3: The differences of PCI-H&N used

Ghazali, 2015 & in the Variation study	**Rogers, 2009**	**Hatta, 2014**	**Present study**
57	**45**	**43**	**52**
Physical & function			
Activity	/	/(ability to work/ daily activity)	/(ability to work/ daily activity)
Appetite	/	/	/
Bowel habit	/	/	/
Breathing	/		+
Chewing/eating	/	/	/
Coughing			+
Dental health/teeth	/	/	/
Dry mouth			/
Energy levels	/	/ (merged^{+a})	/ (merged^{+a})
Fatigue/tiredness	/	/ (merged^{+a})	/ (merged^{+a})
Hearing	/	/	/
Indigestion			
Mobility	/	/	/
Mouth opening	/	/	/
Mucus			
Nausea	/	/	/
Pain in the head and neck	/	/	/
Pain elsewhere	/	/	/
Regurgitation			
Salivation	/	/	/
Shoulder	/	/	/
Sleeping	/	/	/
Smell	/	/	/
Sore mouth			
Swallowing	/	/	/
Swelling	/	/	/
Taste	/	/	/
Vomiting/sickness	/	/	/
Weight	/	/	/
		/ + hairloss	/ + hairloss

Table 2.3: The differences of PCI-H&N used

Ghazali, 2015 & in the Variation study	Rogers, 2009	Hatta, 2014	Present study
57	**45**	**43**	**52**
Treatment related			
Cancer treatment			
Regret about treatment	/	/	/
PEG tube	/	/	/
Wound healing	/	/	/
		/Diet restriction	/Diet restriction
		/Health supplement	/Health supplement
Social care and social well-being:			
Carer	/		+
Dependants/children			+
Financial benefits	/	/	/
Home care/District nurse	/		+
Lifestyle issues (smoking/ alcohol)	/	/	/
Recreation	/	/	/
Relationships	/	/	/
Speech/voice/being understood	/	/	/
Support for my family	/	/	/
Psychological/emotional/spiritual			
Appearance	/	/	/
Angry	/	/	/
Anxiety	/	/	/
Coping			+
Depression	/	/	/
Fear of the cancer coming back	/	/	/
Fear of adverse events	/		+
Intimacy	/	/(merged*^{b})	/(merged*$^{b)}$
Memory	/	/	/
Mood	/	removed	+
Self-esteem			+
Sexuality	/	/(merged*^{b})	/(merged*$^{b)}$
Spiritual/religious aspects	/	/	/
Personality and temperament	/	removed	

_+‘ : added　　_-_: removed

*^{a} : merged as energy level/fatigue/ tiredness　　*^{b} : merged as sexuality/intimacy

Additional : hair loss, diet restriction, health supplement

2.7.1 Versions of PCI for head and cancer

Recently, the use of tablets and electronic formats are becoming more popular as the current mode to deliver the patients reported outcomes (PROs) questionnaires (Campbell, Ali, Finlay, & Salek, 2015). Both versions of administration have their strengths and limitations. In terms of time to complete a PROs, an equivalent study showed longer completion time for the computerised web-based version compared to the paper-based version; however, this result may be due to a new approach that patients are unfamiliar with (Campbell et al., 2015).

A paper version does not incur much cost compared to the computer-assisted technology, which needs to be equipped with the networking and IT facilities (Shneiderman, 1991). A computer-assisted technology can either be a desktop computer or a touch screen (TST) (such as androids, tablets or iPads). In terms of feasibility, a study has shown that patients prefer the TST version as they find it easy to use even for the elderly patients but the screen and buttons used need to be user friendly and suitable for the elderly (Campbell et al., 2015; Caprani, O'Connor, & Gurrin, 2012; Millsopp, Frackleton, Lowe, & Rogers, 2006). As patients become more familiar with the mode of administration, patients will not find it a burden to repeat the prompt list on their subsequent follow-up clinic which will ensure the possibility of data continuity (Millsopp et al., 2006). The paper version is most preferred among IT illiterate patients as some patients find the keyboard difficult to operate (Caprani, O'Connor & Gurrin, 2012). On the other hand, the computerised web-based version is more preferred by the younger patients, and this can cause a bias towards the educated and young age groups of patients (Campbell et al., 2015).

A computer-assisted technology facilitates patients to disclose sensitive personal information to give a more accurate reflection (Cook et al., 1993; Dupont et al., 2009).

The hard copy version has no problem in terms of space for free text as it can be added unlike computerised version with fixed free text space. A data analysis and report sheet can be generated immediately by the computer-assisted technology compared to the paper version which needs to be manually analysed (Semple, Lannon, Qudairat, McCaughan, & McCormac, 2018; Yarnold, Stewart, Stille, & Martin, 1996).

The computer version only allows access to authorised personnel by using security access codes which can ensure more secure confidentiality compared to the paper version, which needs personnel to manage the data collected. Both versions also needs to ensure the records are kept at a secured place, and space is available for filing the records (Caprani, O‘Connor & Gurrin, 2012). The hassle of using a paper-based version can be reduced by using an electronic format (Semple et al., 2018). However, a computer-assisted format will require a back-up system and secured data protection (Caprani, O‘Connor & Gurrin, 2012). A study had shown that both versions either the paper or computerised web-based version had reported no difference in terms of required an assistance upon completing the form (Semple et al., 2018). The best version to choose is what suits the background of the population. Currently, available technologies have brought a potential benefit of using computer-assisted technology as a mode of PCI-H&N administration that includes productive use of waiting room time and eases the assessment process (Taenzer et al., 1997)

The effect on oral cancer patients could further cause negative outcomes on patients‘ HRQoL and psychological aspects. PCI-H&N is not a diagnostic tool, but this prompt list could assist the clinicians to appreciate patients‘ concerns or worries and further manage it at their best possible capacity. Since the prompt list was guided by validated HRQoL domains, indirectly the issues being selected by the patients will inform the clinicians of the patient‘s health status without using a validated HRQoL questionnaire where most clinicians and patients find it burdensome as more time and extra resources are needed to conduct the HRQoL questionnaires (Kanatas & Rogers, 2010).

2.8 Study design issues: Approach and concepts

2.8.1 Pragmatic RCT study design

Randomised control trial (RCT) is one of the study designs that is highly recognised in clinical research due to its rigorous approach compared to other types of study design (Sibbald & Roland, 1998). This quantitative study design is to compare, determine and assess the effect of the intervention in which the study group is exposed to in comparison to the control group and then followed up to assess the differences between the groups (Sibbald & Roland, 1998). The study findings could determine the cause-effect relation which exists between the intervention and the outcomes (Sibbald & Roland, 1998).

In general, the RCT study design can be explained as an ‗exploratory' or ‗pragmatic' design. An explanatory randomised trial is conducted in a well-defined and controlled setting to allow an evaluation of the intervention to demonstrate a beneficial effect. Whilst a pragmatic trial is conducted in real-life clinical practice with usual care provided within the population to which an intervention is intended to be applied to as it is designed to determine the effects of an intervention under the usual conditions (Haynes, Sackett, Guyatt & Tugwell, 2006; Sibbald & Roland, 1998). Pragmatic RCT is intended to suggest and support decision making by the policymaker as it retains the practice in normal clinical procedure but at the same time confines to the rigour of randomisation of an RCT study design (Thorpe et al., 2009).

The ―pragmatic design” has become an emerging approach in the evaluation of complex interventions and services. The approach compromises between (i) the conventional RCT study that has good internal validity and (ii) the observational study, which has excellent external validity (Figure 2.1).

The present study employed a pragmatic RCT study design which recruited post-treatment patients who were present on their follow-up appointment day with the aim to improve patient management (Hotopf, 2002). The new procedure of PCI-H&N can be tested in a full spectrum of standard clinical set up to maximise its applicability and be evaluated against the regular practice of post-treatment follow-up consultation. This approach also allows the outcomes of this study to reflect the actual effect under the usual conditions in which it will be applied (Dickinson et al., 2015; Haynes, Sackett, Guyatt & Tugwell, 2006) by considering that there will be slight variation anticipated in the implementation of the study protocol at the six centres based on each OMFS clinics practice preference. Pragmatic RCT measures a wide variation of outcomes, especially on patient-centred care unlike exploratory RCT which cannot assess internal validity, sample size, sophisticated study design, and controlled environment (Patsopoulos, 2011).

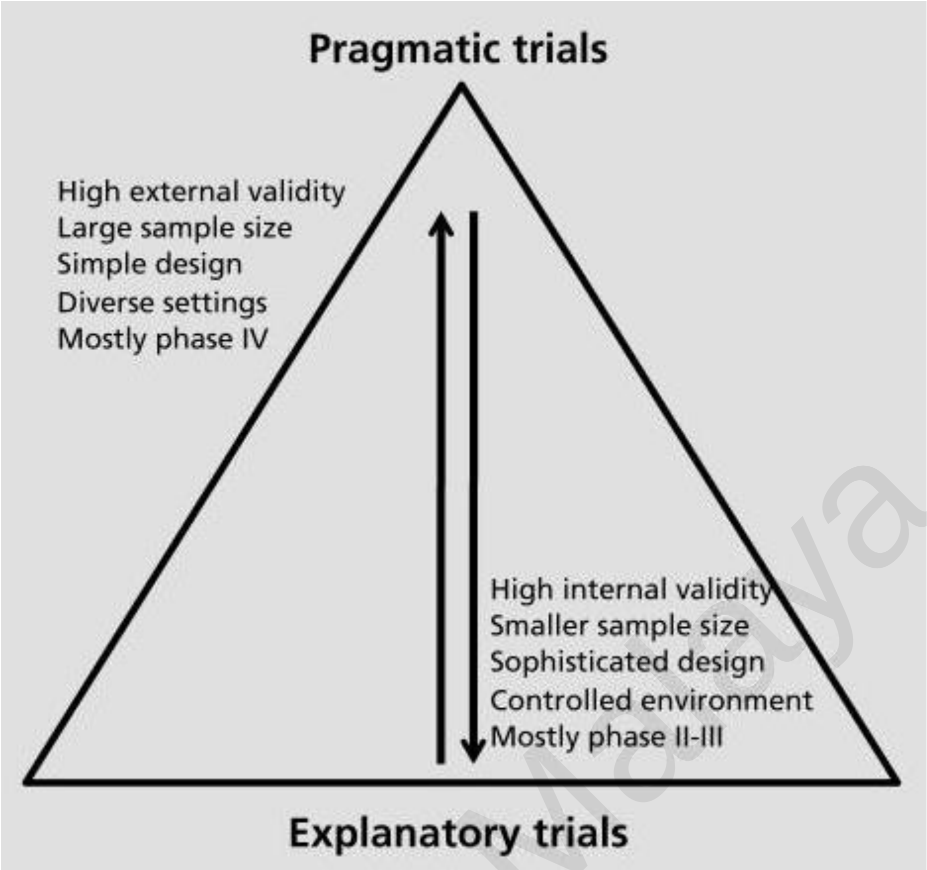

Figure 2.1: Schematic of the relationship between explanatory and pragmatic trials (Adopted from: Patsopoulos, 2011).

In a pragmatic trial, the ‗control group‘ is the ‗standard care‘ which follows the usual routine of the clinical procedure, and while ‗blinding‘ is established in the majority of RCT study to ensure the rigour of randomisation, it may not be practical in some of the pragmatic RCTs (Hotopf, 2002; Thorpe et al., 2009).

All study designs have their specific reporting guideline tools such as PRISMA for systematic review, STROBE or Joanne-Briggs for cross-sectional, CASP for case-control study and CONSORT for RCT. PRECIS (Pragmatic-Explanatory continuum indicator summary) was developed as a reporting guideline for pragmatic RCT in 2009 (Thorpe et al., 2009) with ten domains and later improved to PRECIS-2 (Loudon et al., 2015) in 2015 to overcome a few weaknesses found in PRECIS namely no rating scale, problems with some domains, needs better guidance, and not a validated tool. PRECIS-2 is a validated guideline tool of nine domains with the scoring of a 5-point Likert scale of 1=very explanatory ―ideal conditions” to 5=very pragmatic ―usual care conditions” (Loudon et al., 2015). The nine domains (Loudon et al., 2015) are as described in Table 2.4.

Table 2.4: The nine PRECIS-2 domains

The nine PRECIS-2 domains:		
1	Eligibility	To what extent are the participants in the trial similar to those who would receive this intervention if it was part of usual care?
2	Recruitment	How much extra effort is made to recruit participants over and above what would be used in the usual care setting to engage with patients?
3	Setting	How different are the settings of the trial from the usual care setting?
4	Organisation	How different are the resources, provider expertise, and the organisation of care delivery in the intervention arm of the trial from those available in usual care?
5	Flexibility (delivery)	How different is the flexibility in how the intervention is delivered and the flexibility anticipated in usual care?
6	Flexibility (adherence)	How different is the flexibility in how participants are monitored and encouraged to adhere to the intervention from the flexibility anticipated in usual care?
7	Follow-up	How different is the intensity of measurement and follow-up of participants in the trial from the typical follow-up in usual care?
8	Primary outcome	To what extent is the trial‘s primary outcome directly relevant to participants?
9	Primary analysis	To what extent are all data included in the analysis of the primary outcome?

2.8.2 Focus group discussion to gain valuable insight

Generally, there are two methodological study approaches; the quantitative and the qualitative. These methodology approaches are highly dependable on what the researcher intended to achieve in the study conducted (Guetterman, Fetters, & Creswell, 2015). Quantitative research is used to quantify the problem by way of generating numerical data or data that can be transformed into useful statistics. It is used to quantify attitudes, opinions, behaviours, and other defined variables – and focuses on gathering numerical data and generalising it across groups of people or explaining a particular phenomenon (Babbie, 2015). Qualitative research is primarily exploratory research. It is used to gain an understanding of the underlying reasons, opinions, and motivations. It provides insights into the problem or helps to develop ideas or hypotheses for potential quantitative research. Qualitative research is also used to uncover trends in thought and opinions and dive deeper into the problem (Denzin & Lincoln, 2008). Both methods are different in terms of study design, data collection and analysis, and approaches in achieving its intended aim research questions (Castillo-Page, Bodilly, & Bunton, 2012). There are many types of data collection in qualitative study design. One that was adopted in the present study is the focus group discussion (FGD).

FGD is a small-group discussion guided by a trained moderator to discuss a specific topic among the group members (Kitzinger, 1995). The uniqueness about FGD is the information gathered through interactions between similar members‘ background, and each of the members stimulates ideas that are facilitated by the moderator and guided by semi-structured or structured questions (Kitzinger, 1995; Wong, 2008). FGD gained its popularity in health intervention studies as valuable data could not be accessed by other data collection methods. The main purpose of the focus groups is to explore data from a wide range of health-related issues to gain insight of the public experiences concerning health risk habit practices, sensitive issues that are limited to access through quantitative studies (e.g. HIV/ AIDS, or sexual health issues), public experiences of health services, and feedback from the service providers on the intervention conducted (Kitzinger, 1995; Wong, 2008).

2.8.3 Framework in assessing new intervention: FRAME-IT

Phase-2 of the present study was a qualitative study (focus group discussion; FGD) involving the health personnel. The FGD was meant to gain valuable insight on the usefulness and feasibility of PCI-H&N during the follow-up consultation through their experiences and recommendations for improvement. The FGD was guided by a structured list of questions based on an evaluation of the intervention framework.

The World Health Organisation (WHO) (2018) defines health interventions as acts to ‗*assess, improve, maintain, promote or modify health, functioning or health condition*'. The evaluation of an intervention is necessary as it shows the effectiveness of the new intervention as it intended to function. Evaluation of an intervention can be conducted in three phases: early, mid and late stage. As for the present study, an early phase evaluation was most suitable. The early-stage intervention focuses on the creation and testing of intervention content specifically on the product itself, service, solution, application, programme, process, tool, approach, or software. At the early phase evaluation, it is more concerned with its content of product feasibility and its application on a small-scale study group (WHO), 2016).

Whilst a few numbers of evaluation framework at the early stage of implementation are available, ‗FRAME-IT' is the closest evaluation framework to be adopted for the structured FGD as it includes a comprehensive set of processes and implementation fidelity assessments for newly implemented interventions in order to guide it for future implementation (Griffin et al., 2014). Other available evaluation frameworks for early intervention are:

i) RE-AIM which is a public health intervention that assesses five dimensions: reach, efficacy, adoption, implementation and maintenance (Glasgow, Vogt, & Boles, 1999),

ii) 9-dimensional evaluation framework by (Baranowski & Stables, 2000) which emphasises on recruitment, maintenance, context, resources, implementation, reach, barriers, exposure, initial use, continued use and contamination.

iii) evaluation framework by Linnan and Steckler (2002) which emphasises the seven key dimensions in evaluating the intervention: ‗context‘ (environmental aspects of the intervention setting), ‗reach‘ (the proportion of participants who received the intervention), ‗fidelity‘ (whether the intervention is delivered as planned), ‗dose delivered and received‘ (the amount of intervention delivered and the extent to which participants responded to it), ‗implementation‘, (a composite score of reach, dose and fidelity), ‗recruitment‘ (methods used to attract participants) and cost.

iv) Implementation outcomes by Proctor et al. (2011) which proposes implementation outcomes of acceptability, adoption, appropriateness, feasibility, fidelity, implementation cost, penetration, and sustainability.

FRAME-IT and RE-AIM are both evaluating early phase of intervention implementation; however, RE-AIM focuses on the later period of early intervention phase while FRAME-IT evaluates the immediate effect of the implementation (Gonot-Schoupinsky & Garip, 2019). FRAME-IT consists of seven key-constructs of feasibility, reach-out, acceptability, maintenance, efficacy, implementation and tailorability and four of the key constructs are from RE-AIM (reach, efficacy, implementation, and maintenance). This inclusion was on purpose to reflect the continuity of the evaluation as the RE-AIM intervention assessment can be used in the later period of the early intervention. As an early phase of the evaluation framework, FRAME-IT is more focused on exploring and testing the intervention content either through quantitative or qualitative study (Figure 2.2) (Gonot-Schoupinsky & Garip, 2019).

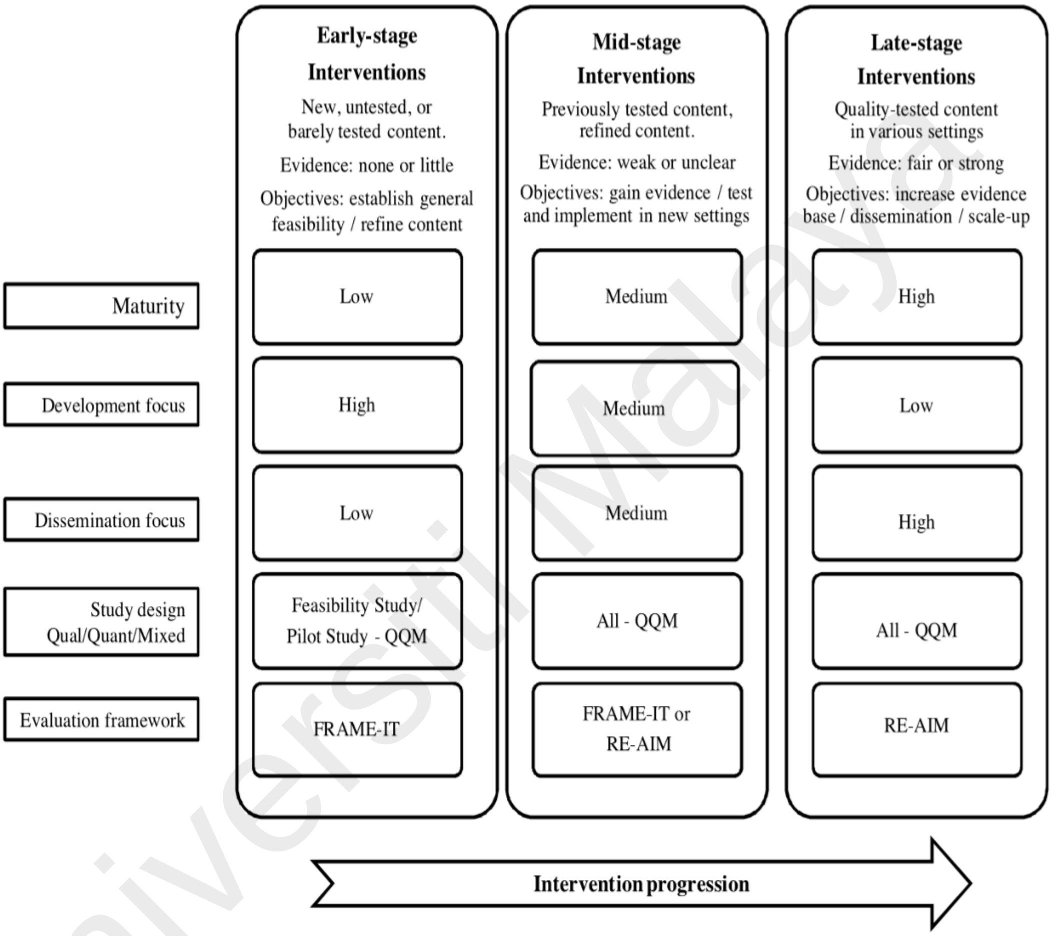

Figure 2.2: Three-stage health intervention life-cycle taxonomy[1]

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[1] Note: Inspired by WHO (2016), source (Gonot-Schoupinsky & Garip, 2019).

2.9 Summary and knowledge gap

Oral cancer and its treatment impact patients‟ post-treatment outcomes mainly patients‟ HRQoL especially physical impacts, psychological distress and their satisfaction with consultation. Hence, one of the challenges in patients‟ management faced by clinicians is to achieve positive post-treatment outcomes by effectively addressing patients concerns. PCI-H&N is a prompt list that addresses patients‟ concerns which is central to holistic patient-centred care and enables patients to discuss their concerns with the clinicians, promotes shared decision making and empowers patients in seeking information. Routine follow-up consultations could incorporate the PCI-H&N as an individualised approach to enhance patient-centred care, as past evidence has shown that the type and number of patients‟ concerns reflect their HRQoL and psychological distress.

As such, the relevant findings from the prompt list could assist clinicians before they decide on the best treatment for the patients by considering the after effects of post-treatment, disease-related symptoms and how to optimise patients‟ HRQoL.

CHAPTER 3: METHODOLOGY

3.1 Introduction to the study design

This research is a mixed-method study designed to compare the two versions of PCI-H&N, namely paper and computerised web-based versions, and its short-term impact on patients' HRQoL, psychological distress level and satisfaction with their follow-up consultation. This study was conducted in two phases involving post-treatment oral cancer patients in multiple Malaysian centres of Oral Maxillofacial Surgery (OMFS) Clinics in hospitals. The quantitative study of the first phase comprised of two parts: (i) the comparison between PCI-H&N users and non-users, and (ii) the comparison between two versions of PCI-H&N (paper and computerised web-based versions). In the qualitative study of phase two, a structured face-to-face interview was carried out among the health personnel who were involved in this study to identify availability and required resources, and further explore possible barriers of its implementation through their experiences throughout this study (Figure 3.1).

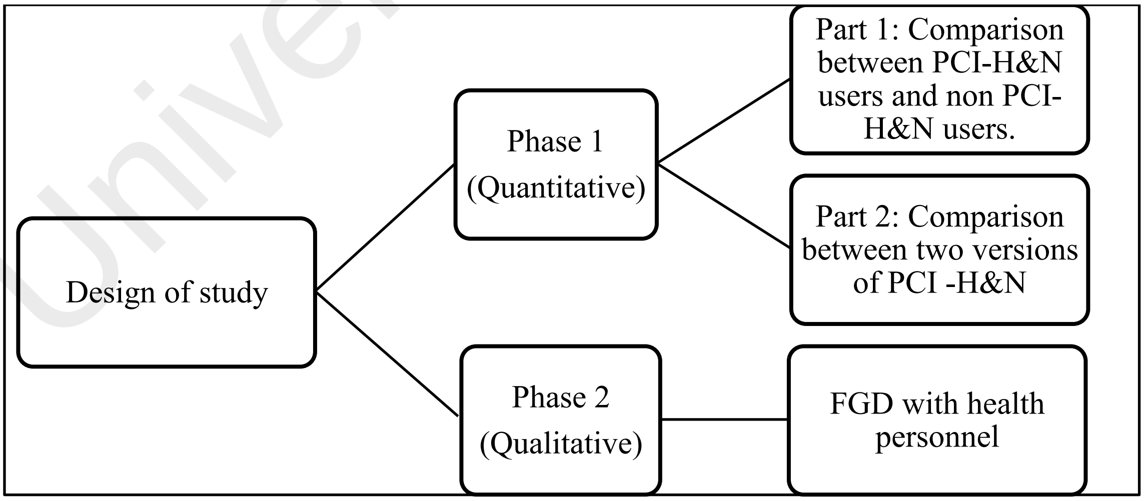
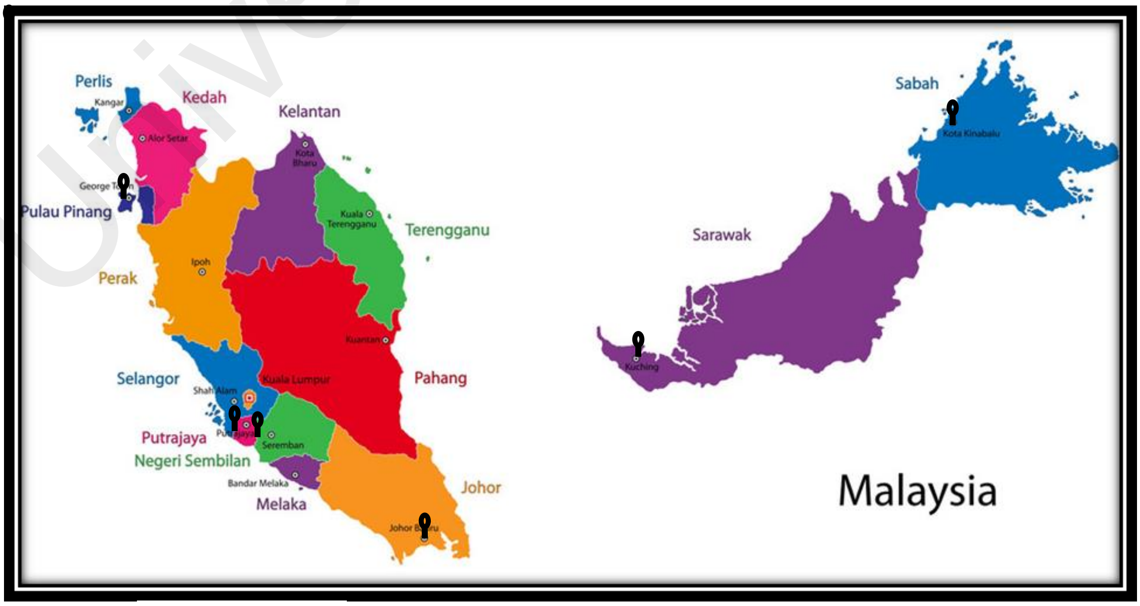


Figure 3.1: Diagram of the study design

3.2 Study background

The study was conducted in six Oral Maxillofacial Surgery (OMFS) clinics (five government hospitals and one institutional hospital) in Malaysia representing Peninsular and East Malaysia. The potential study areas were proposed by the Oral Health Programme, Ministry of Health Malaysia, as these centres are the tertiary centres for the management of oral cancer cases. The selected OMFS clinics are located in the city centres namely (i) Kuala Lumpur General Hospital and (ii) OMFS clinic of Dental Faculty, University of Malaya, which are located on the west coast of Peninsular Malaysia, (iii) Seberang Jaya Hospital, Penang, located on the north coast of Peninsular Malaysia, (iv) Sultanah Aminah Hospital, Johor, located on the south coast of Peninsular Malaysia, and (v) Queen Elizabeth Hospital, Sabah, and (vi) Sarawak General Hospital, Sarawak, in East Malaysia (Figure 3.2). In total, there are 46 government hospital-based OMFS clinics in Malaysia (OHD website, 2019) for the current estimated population of 32.6 million people (Department of Statistic, Malaysia, 2019).



📍 : Study site

Figure 3.2: Location of study sites

Malaysia is a diverse country and known for its multi-racial and multi-religious population which consists of various ethnicities with 62.6% being Bumiputera (DOSM website, 2019) comprising Malays and indigenous ethnicity from Sabah (32 ethnicities) and Sarawak (27 ethnicities). These multi-ethnic populations have their individual cultural beliefs that include practising oral cancer-related risk habits such as betel nut and tobacco chewing as part of their customs (Ghani, Razak, et al., 2019; Zain, 2001).

Management of oral cancer patients is complex as it requires multi-disciplinary management and is continually evolving (Chinn & Myers, 2015). Commonly, patients diagnosed with oral cancer lesions will undergo treatments such as surgical, chemotherapy, radiotherapy or combination modalities or palliative management based on their pre-treatment assessment (for example, cancer staging, histopathological findings) (Adelstein et al., 2017). This study involved oral cancer patients who had completed oral cancer treatment and were undergoing follow-up reviews.

3.3 Phase 1 study (Quantitative)

3.3.1 Study design

Phase 1 of the present study is a three-armed Pragmatic Randomised Controlled Trial (pRCT) conducted among post-treatment oral cancer patients at the six selected OMFS clinics during patients‘ follow-up consultation appointments. A pragmatic RCT study design was chosen to allow the outcomes of this study to reflect the actual effect under the usual conditions in which the new procedure will be applied (Dickinson et al., 2015; Haynes, Sackett, Guyatt & Tugwell, 2006) to the standard care of follow-up consultation, taking into consideration the slight variation in the study protocol‘s implementation at the six OMFS centres based on each practice preference. This study adhered to PRECIS (Pragmatic- explanatory continuum indicator summary) as categorised under RCT study design (Thorpe et al., 2009).

In the first part of Phase 1, patients were randomly assigned to the three study groups according to group A (paper-based PCI-H&N), group B (computerised web-based PCI-H&N), and group C (normal consultation, i.e. the control group). Then they were given the PCI-H&N prompt list either in paper version (group A) or computerised web-based version (group B). Patients in group C received normal consultation sessions without the use of PCI-H&N prompt list. Each study group was given three sets of questionnaires. One set was to be completed before their consultation session with the clinicians and another after the session. They were also required to return the last set of questionnaires after a period of two to four weeks from the review date either by mail (self-addressed stamped envelope) or by hand to the assistant at their subsequent follow-up clinic. No blinding was involved in this study as the patients and clinicians could identify the patients‘ group since the PCI-H&N were in visibly different templates (Thorpe et al., 2009). Flow diagram of the *p*RCT study as shown at Figure 3.3.

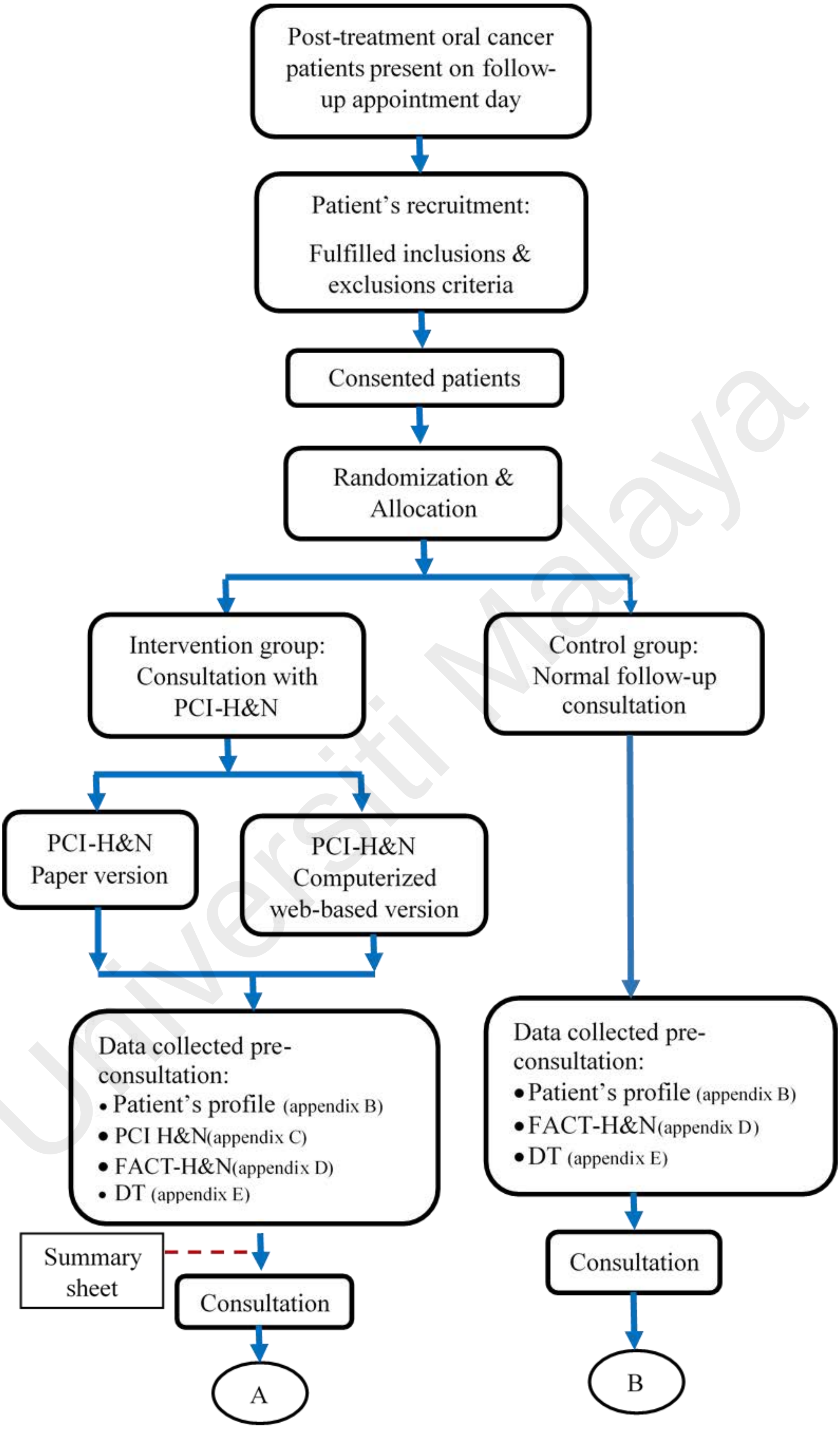


Figure 3.3: Flow diagram of patients through PCI-H&N intervention RCT study

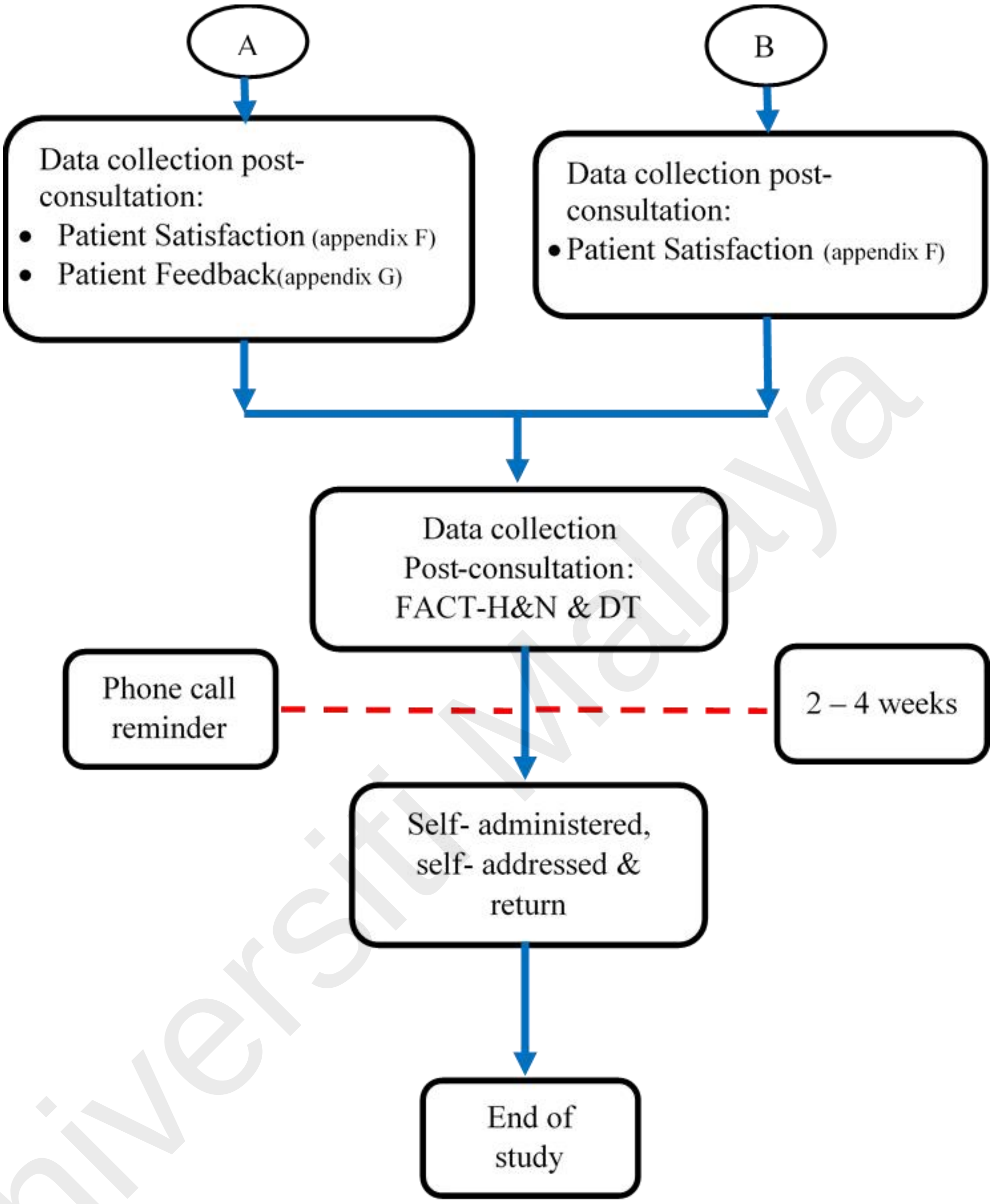


Figure 3.4: Flow diagram of patients through PCI-H&N intervention RCT study (continued)

3.3.2 Study population

The target study population involved health personnel (clinicians and assistants) and all post-treatment oral cancer patients from six OMFS clinics in Malaysia. The source population was all post-treatment oral cancer patients who attended their follow-up consultation appointments. The OMFS clinics‘ areas are shown in Table 3.1.

Table 3.1: Six OMFS study sites

No	Location	Hospital
1	Federal Territory of Kuala Lumpur	Kuala Lumpur Hospital
2		Oral Maxillofacial Surgery, Dental Faculty, UM
3	Penang	Seberang Jaya Hospital
4	Johor	Sultanah Aminah Hospital
5	Sabah	Queen Elizabeth Hospital
6	Sarawak	Sarawak General Hospital

3.3.3 Inclusion and exclusion criteria

All eligible patients who attended their post-treatment follow-up consultations and health personnel from the OMFS clinics during the data collection period (April – December 2019) were recruited for this study. The inclusion and exclusion criteria were as follows:

3.3.3.1 Inclusion criteria

i) Patients:

  a. Malaysians age 18 years old and above
  b. Post-treatment patients with 100% completion of oral cancer treatment (surgical/radiotherapy/chemotherapy or combination) from one month until five years follow-up (or until when the clinicians review the patients)

    c. Patients under routine follow-up in the identified hospitals.

ii) Clinicians:

    a. OMFS staff or Post-graduate trainees or Clinicians who run the post-treatment follow-up consultations.

iii) Dental assistants

Assistants involved in the patients‘ registrations and assisting the clinicians.

3.3.3.2 Exclusion criteria:

i) Patients

    a. Post-treatment oral cancer patients with a medical diagnosis of uncontrolled psychiatric or mental condition
    b. Patients with recurrence of cancer during the data collection period
    c. Patients who were unaccompanied and with significant difficulty in hearing, reading, or speaking.

ii) Clinicians

    a. Clinicians undergoing New Dental Officer Programme (NDOP)
    b. Clinicians with working experience less than a year

iii) Assistants

    a. Assistants on a contract work basis

3.3.4 Sample size

G-power 3.1 (Faul, Erdfelder, Buchner, & Lang, 2009) was used to estimate the sample size required for this study. Sample size calculation was based on the literature references on the primary outcomes of PCI-H&N among oral cancer patients.

Two studies were used as a reference for this calculation. The first was a study by Doss et al. 2011, which reported on the impact of oral cancer at different stages of illness both at diagnosis and at one- and six-month post-treatment. The study used the Functional Assessment of Cancer Therapy (FACT-H&N) v 4.0 to assess health-related quality of life (HRQoL) among oral cancer patients. The sample size was estimated by taking the mean HRQoL score of the control group from the baseline sample data, whereas the first follow-up at one-month HRQoL mean score was used for the post-treatment. A priori analysis was computed to estimate sample size with a statistical power of 80% and 5% of type 1 error.

Table 3.2: HRQoL mean score at baseline and 1-month (1st follow-up)

FACT-H&N	Baseline	(1 month) 1st follow-up	Effect size	Estimation N
Mean(SD)	94.1(17.6)	87.3(20)	0.36	63

The other study by Ringash, O'sullivan, Bezjak, and Redelmeier (2007) estimated that for a minimum sample size to reflect a clinically significant change of 5-10%, a sample size of 80 patients per-arm as the minimum recruitment for a two-armed RCT after allowing 20% attrition (n=160) would be required.

The identified positive outcomes were the patients‘ quality of life and satisfaction with their follow-up consultation. In this study, the assumption was based on the patients‘ satisfaction with the follow-up consultation. Thus, similar assumptions were made for the outcome of satisfaction between the three study groups (paper version, computer web-based, and control). Based on the assumptions made, the sample size calculation for satisfaction outcome is the same with the sample size calculation based on FACT H&N, but without considering the 20% attrition because the patient satisfaction outcome will be obtained post-consultation (immediate outcome) on the same day. As such, no patient attrition was expected. The sample size calculation was as below:

i) Based on the mean FACT-H&N:

   n= 63 + (63*0.2) = 76 (38 per-arm)

ii) Based on the assumption for satisfaction outcome with consideration of 5-10% clinical change:

   n= 80 – (80*0.2) = 64 (64 per-arm)

Therefore, based on the sample size calculation for the two primary outcome variables, the final sample size needed for 3-armed parallel RCT with 80% power and 5% significant level was 192 patients (64 patients per-arm). However, this estimation was based on early patient recruitment before the study (Ringash et al., 2007) was conducted, which could not be applied in the present study. The present study was a pragmatic RCT study design which recruited post-treatment patients who turned-up on their follow-up appointment day. Sample size estimation could not be performed based on patients‘ return to the clinic as there were no specific or reliable sources on the numbers of post-treatment oral cancer patients under follow-up in Malaysia. Thus, all patients who presented on their follow-up appointment day were recruited from April – December 2019 based on the inclusion and exclusion criteria.

After all the efforts taken to increase the sample size, the final sample size obtained for this study was n=123.

a) Based on similar priori analysis computed on the sample achieved (n=123), effect size=0.36 and 5% significant level, the study power was achieved at 62.5%.

b) Based on different means for matched pair within the PCI group:

n=55 (pre-post PCI)

effect size: 0.32 for total HRQoL (FACT-H&N-MAQ score) at 95% CI

post hoc power study: 64.5%

3.3.5 Outcomes measured

Sociodemographic and cancer characteristics of patients including gender, age, ethnicity, education level, tumour sites, clinical TNM staging, cancer staging (I, II, III and IV) were collected after informed consents were received. Questionnaires were given at pre- and post- consultation sessions. Study outcomes were measured based on patients‘ self-reporting. The primary outcomes were assessing patients‘ HRQoL, psychological distress, and satisfaction with the follow-up consultation while secondary outcomes were assessing the feasibility of PCI-H&N prompt list and the preferred PCI-H&N version. The measurement of the assessment is shown in Figure 3.5.

i. Primary outcomes:

a. Patients‘ HRQoL, psychological distress level and satisfaction with their consultation session were obtained from part one of the study.

ii. Secondary outcomes:

a. The usefulness and feasibility of PCI-H&N, based on feedback from patients, clinicians, and dental assistants. The average time taken to complete the new procedure by patients and the length of the consultation session were measured. For the clinician, the feasibility questions were on helping a more focussed discussion with patients, whether it helps the patients to recall issues of patients‘ concerns, ranking on its usefulness and agreement for future use in their routine consultation clinics.

b. Preferred PCI-H&N versions, based on feedback from patients, clinicians, and dental assistants.

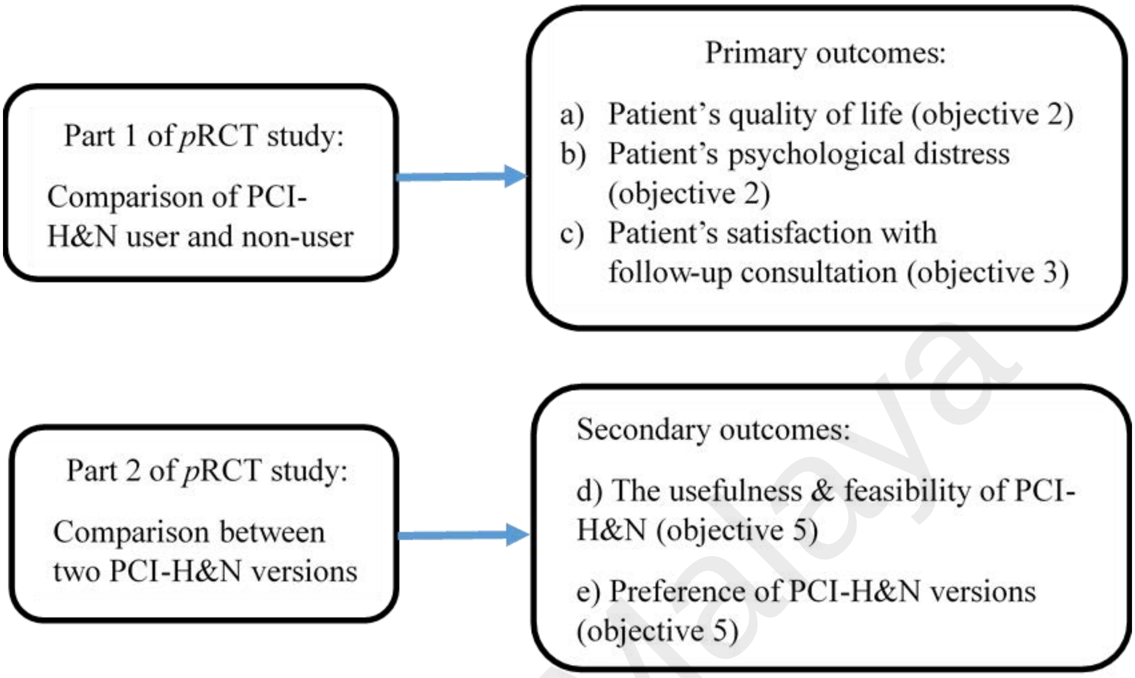


Figure 3.5: Outcomes derived from the quantitative study

3.3.6 Study variables

The summary of the independent and dependent variables included in this study is presented below:

i) Independent variables

Variables	Measurement
Sociodemographic background	Gender, age, marital status, ethnicity, religion, and education level.
Cancer characteristics	Tumour site, clinical staging (TNM), cancer stage (I, II, III, IV), type of oral cancer treatment done (surgical, radiotherapy/chemotherapy without surgery and combination of surgery with radiotherapy/ chemotherapy) and time after treatment completed.

ii) Dependent variables

Variables	Measurement
Patients‘ post-treatment concerns	• Descriptive information on patients‘ concerns that were relevant to them. May select more than one. • Two general HRQoL questions in ordinal scale of 5-point Likert scale.
Patients‘ HRQoL	• Total score to measure patients‘ HRQoL was a total score of FACT-H&N-MAQ and excluding questions related to patients‘ habit (GS7 and MQ7) • Re-code to positive statement using the FACT guideline scoring (Doss et al., 2011). • In ordinal scale of 5-point Likert scale
Patients‘ psychological distress level	• Consist of two sections; the visual analogue scale and the prompt list of problem items. • Visual analogue scale (VAS): 0-10 • Cut off point: $\geq$ 4 (Yong, Zubaidah, Saidi, & Zailina, 2012)
Patients‘ satisfaction with follow-up consultation	• In ordinal 5-point Likert scale
Usefulness and feasibility of PCI-H&N	• Among patients, clinicians, and the assistants who use the PCI-H&N • It was measured by patients' ‗yes' or ‗no' answer (nominal) and ordinal answer for their preference of PCI-H&N version

The scale of measurement for patients‘ sociodemographic background and cancer characteristics is as described in Table 3.3. The scale of measurement for the dependent variables is as listed in Appendix A.

Table 3.3: Scale of measurement for sociodemographic background and cancer characteristic.

1) Sociodemographic background

Conceptual definition	Operational definition	Scale of measurement	Unit
Gender		Nominal	Male Female
Age	Age as last birthday	Continuous	Years
		Ordinal	18-50 51-65 66-100
Ethnicity		Nominal	Malay Chinese Indian Bumiputera Sabah/Sarawak/ others
Marital status		Nominal	Married Single Divorcee/ Widow
Religion		Nominal	Muslim Christian Buddhist Hindu Others
Educational level	The highest education obtained	Ordinal	No formal education Secondary Tertiary

2) Cancer characteristics

Conceptual definition	Operational definition	Scale of measurement	Unit
Cancer site	Oral cancer site as first diagnosed	Ordinal	Lips Buccal Alveolus Gingivae Tongue Salivary gland Mandible Maxillary Palate Floor of the mouth
TNM staging	Oral cancer staging according to the International Union Against Cancer's classification system	Ordinal	I II III IV
Types of cancer treatment done		Nominal	Surgery only Radiotherapy/ Chemotherapy without surgery Surgery & radiotherapy/ & chemotherapy
Time since after treatment completed			1 month till 1 year More than 1 year till 3 years More than 3 years till 5 years >5 years and more

3.3.7 Study instrument

i) Sociodemographic and cancer characteristics.

Consists of section A: Sociodemographic, which were completed by the patients and section B: Patient's clinical information, which was completed by the clinicians or assistants (Appendix B). Section A includes the patient's gender, marital status, ethnicity, religion, and educational level. Section B consists of cancer characteristics including cancer sites, tumour staging, stage of cancer, treatment management, and dates of diagnosis, treatment started and treatment completed.

ii) New procedure: Patient Concerns Inventory of Head & Neck (PCI-H&N)

PCI-H&N consists of 52 structured patients‘ concerns (Appendix C). This prompt list is grouped into seven principal domains namely of (i) physical status (23 items), (ii) personal functions (six items), (iii) treatment-related (six items), (iv) social care and social well-being (seven items), (v) economic status (one item), (vi) emotional status (eight items), and (vii) spiritual well-being (one item). It was adapted from Hatta, Doss and Rogers‘s list of 43 items (Rogers et al., 2009) (cross-culturally adapted to Malaysia) with an additional nine items from Ghazali, Roe, Lowe, and Rogers (2015) (e.g. _breathing‘, _coughing‘, _carers‘, _dependant/children‘, _home care/district nurse‘, _coping‘, _self-esteem‘, _fear of adverse events‘, and _mood‘). The draft was face- and content-validated by a public health specialist and an OMFS specialist and went through forward-backwards translation from English to the Malay language. The specialists were required to comment on the Malay translation for the additional items. Minor adjustments on the prompt list were made following their comments and suggestions. The forward-backwards translation was conducted among three research assistants from the Oral Cancer Research & Coordinating Centre (OCRCC), UM. A consensus was obtained for the final decision on the Malay language translated items.

This new procedure involved both PCI-H&N in paper version and a computerised web-based version. Both versions have similar content but different in terms of aesthetic layout. The computerised web-based version was developed with the help of a computer web developer specialist, and a server (ServerFreak Technologies) for data collection was temporarily subscribed for RM 250 per year. Each of the seven domains was designed as an individual layout page with a _next' button to proceed to the following domain on the next page. Patients were able to choose any domain if it was not related to them and to return to the domain page of the previous page. Upon completion, a summary sheet was generated for the use of the clinicians during the consultation. A tablet was used during the intervention data collection. Patients were able to choose (select by ticking ‗√‘ in the box) more than one item of their concerns for both paper and computerised web-based versions.

iii) Functional Assessment of Cancer Therapy Scale (FACT-H&N v4.0)

Patient‘s reported outcomes on quality of life were measured using the Functional Assessment of Cancer Therapy Scale (FACT-H&N v4.0) (Doss et al., 2011). It is a validated and cross-culturally adapted questionnaire to be used among Malaysian head and neck cancer patients. FACT-H&N v4.0 consists of six domains with 49 self-reported questions using a 5-point Likert response scale of ―not true at all”, ―somewhat true”, ―quite true”, ―true” and ―very true” (Appendix D). The domain categories are (i) physical well-being (PWB), (ii) social well-being (SWB), (iii) emotional well-being (EWB), (iv) functional well-being (FWB), (v) head and neck subscale (HNS) questions, and (vi) Malaysian-added questions (MAQ) (Table 3.4). All the questions are only related to patients‘ experience for the past seven days. A general question on patients‘ self-rated overall HRQoL and a transition judgement question (on patients‘ self-rated change in HRQoL of the current visit compared to the previous visit) was incorporated at the end of this questionnaire. Scoring was based on the FACT scoring guideline (Doss et al., 2011). In this study, the question on sexual relationships (GS7) was excluded due to meagre response and the question on betel quid chewing habit (MQ6) from the additional set of Malaysian-added questions was also excluded as it is related to risk habit practice. The total HRQoL score used for data analysis was the FACT-H&N-MAQ total score.

This questionnaire ended with two general questions on patients‘ overall self-rating of their HRQoL and a transition judgement question of patients‘ HRQoL compared to their previous visit (Table 3.4).

Table 3.4: Content of FACT-H&N v4.0

No	Domains	Total questions
1	Physical condition	7
2	Social/family relationship	7
3	Emotional well-being	6
4	Personal functions	7
5	Head and neck subscale	12
6	Malaysian questions	8
7	Overall questions	2
Total		49

iv) Distress Thermometer (DT) Questionnaire

Distress Thermometer (DT) is a single-item measure, generated to assess the psychological distress among cancer patients created by Roth et al. (1998), and this instrument was recommended by National Comprehensive Cancer Network (2011) (NCCN) as a screening tool for psychological distress problems. DT is acceptable at detecting broadly-defined distress and depression among patients, and this instrument measures the patient's experience for the past seven days. This study adopted a cut-off point of four, as suggested by Yong et al. (2012) and Ghazali, Roe, Lowe, Tandon, Jones, Brown, et al. (2017). Groups were categorised as ‗low risk‘ (score 0-3) and ‗at risk‘ (score 4-10).

DT questionnaire had been culturally adapted and validated for use among Malaysian population (Yong et al., 2012) DT (Appendix E) consists of (a) Visual Analog Scale (VAS) of a thermometer and (b) checklist of 36 items of "yes" or "no” as below :

a) Visual Analog Scale (VAS) of a thermometer.

VAS is a Likert scale of 0–10, with 0 representing –no distress” and 10 representing –extreme distress.” Patients may circle the number they feel their state of stress levels for the past seven days. Some studies observed that a cut-off point of ‗four‘ or ‗five‘ showed a similar specificity and sensitivity (Ghazali, Roe, Lowe, Tandon, Jones, Brown, et al., 2017; Yong et al., 2012).

b) Checklist items of –yes” or –no”

The checklist comprises of 36 items that potentially caused distress which were grouped into five domains of practical problems, family problems, emotional problems, spiritual/religious concerns, and physical problems. Patients may select more than one item.

v) Patient Satisfaction Questionnaire

Patient‘s satisfaction with the quality of the follow-up consultation session was adapted from various literature reviews and applicable validated questionnaires (Giordano, Elliott, Goldstein, Lehrman, & Spencer, 2010; Kerssens, Groenewegen, Sixma, Boerma, & Eijk, 2004; Sustersic et al., 2018; Zachariae et al., 2001) that are related to the assessment of patients' satisfaction with their follow-up consultations. The questionnaire consists of seven self-rated statements with a 5-point Likert scale response option of ―very satisfied”, ―satisfied”, ―neither”, ―dissatisfied” and ―very dissatisfied”, and two open-ended questions (Appendix F). The questionnaire assessed patients‘ satisfaction with the information they received. The statements are related to patients‘ concerns and items discussed, claim of discrepancies in the discussion, patients‘ participation in the discussion and sufficient time duration spent for the consultation session. The draft of the Patient Satisfaction questionnaire was face- and content-validated by a public health specialist and an OMFS specialist. Minor adjustments on the questionnaire were made following their comments and suggestions. The validated questionnaire underwent forward-backwards translation from English to the Malay language. A primary English school teacher performed the forward translation whereas a public health specialist did the backwards translation, and the translated English version was cross-checked with the original draft. A consensus was obtained for the final decision from both translators. The reliability was assessed during a pilot test conducted in OMFS, UMCC (Cronbach‘s α= 0.83).

vi) PCI-H&N Feasibility Feedback Questionnaire

There were three separate PCI-H&N Feasibility questionnaires for the patients, clinicians and dental assistants, which were face- and content-validated in a previous study (Hatta, Doss & Rogers., 2014).

Patients Feasibility Feedback Questionnaires were completed by the patients after their post-consultation sessions, whereas the health personnel‘s version (clinicians and the assistants) was filled up at the end of data collection period at the individual study site. These questionnaires were adapted in the present study with an additional question on the preferred PCI-H&N versions.

The Patients‘ Feasibility Feedback Questionnaire consists of six items of ‗yes‘ and ‗no‘ answer and 5 points Likert response scale (Appendix G). Other information included were on patients‘ preferences, level of ease to use the prompt list and level of confidence for completing the PCI-H&N without being assisted.

The Clinician‘s Feasibility Questionnaire consists of nine questions with ‗yes' and ‗no' answers as well as scale point from one to ten (poor to good) (Appendix H). As for the assistant‘s version, it consists of five questions with ‗yes' and ‗no' answer as well as a question on their view on the suitable time for the patients to fill up the prompt list (Appendix I).

3.3.8 Pilot study

A pilot test was conducted in OMFS clinic in the Faculty of Dentistry, UM, before conducting the field study at the six selected centres. A total of 18 eligible post-treatment oral cancer patients were involved in the pilot test. The pilot test was conducted to:

- test the clarity of the validated Patient‘s Satisfaction questionnaire,
- determine the reliability of the Patient‘s Satisfaction questionnaire,
- assess the clarity of the workflow protocol among the assistants,
- test the readiness of the computerised web-based PCI-H&N version,
- test the flow of the study process,

- measure the time taken to complete the PCI-H&N prompt list, and pre- and post-consultation questionnaires involved,
- measure the time taken to complete the questionnaires after the post-consultation session,
- note the difficulties encountered during implementation of both versions of PCI-H&N,
- obtain the estimate percentage return of post-consultation questionnaires after two to four weeks.

The reliability of the patient‘s satisfaction questionnaire was determined by using Cronbach‘s alpha coefficient test value degree 0.83. The value was a reasonably high level of reliability. Therefore, no questions were removed, and there was only minor adjustment according to the feedbacks during content validations.

During the pilot test, it was observed that patients need to be assisted in answering the questionnaires. The average time taken for the patients to complete the prompt list was five to 20 minutes. The majority of the patients were also unclear and reluctant to answer questions on relationship/sexuality (GS7 FACT-H&N v4.0). Therefore, question GS7 from FACT-H&N was excluded from the total score of FACT-H&N-MAQ calculation. Another observation was the study briefing and completion of the PCI-H&N and questionnaires by the patients required an appropriate area.

3.3.9 Training

Individual training sessions were conducted at the six OMFS clinics. The participants were selected clinicians and assistants based on the criteria mentioned in section 3.2.4. The half-day session was on the briefing of the study flow, patients‘

selection, highlighting the role of each health personnel, administration of PCI-H&N-H&N, data collection management and safety of record keeping. Participants were also informed of the data collection period. Each clinician and assistant was provided with a study manual and study workflow. The assistants who will be assisting patients were trained in detail on the PCI-H&N prompt list and the questionnaires involved.

Besides the briefing, a discussion was also conducted to identify an appropriate location to administer the PCI-H&N prompt list to patients. This area designation was necessary to ensure privacy while conducting the study, as some questions were quite sensitive to patients. The training also involved familiarising with the flow of the study. The training session highlighted the shortfalls and how to overcome them. The principal researcher conducted the data collection herself at two centres in FTKL due to the shortage of assistants at these sites.

3.3.10 Conduct of study

An official letter was sent to the Oral Health Programme, Ministry of Malaysia, to request permission to conduct the present study at the six identified locations (Appendix J). The letter of approval was then distributed to all the Head of Department of OMFS in each participating clinic together with the NMRR approval letter (Appendix K) and UM ethics committee (Appendix L).

The study was conducted concurrently at all study sites from April 2019 until December 2019. The flow of the study process is in (Appendix M). At the registration counter, all oral cancer patients who came for post-treatment follow-up were invited to participate in the study based on the inclusion and exclusion criteria. The assistants briefed eligible patients on the study‘s purpose and process. Patients were required to answer a set of questionnaires together with the PCI-H&N prompt list before the follow-up consultation and another set of questionnaires after the consultation. Patients could request for assistance in answering the questionnaire and prompt list. They spent approximately 15 minutes to answer the questionnaires before the consultation session and approximately five minutes after the consultation session. Patients were informed that their participation was voluntary, which will not have any influence on their consultation session. Patients could consider their involvement in the study and discuss with those accompanying them. Those who agreed to participate were given a written consent form (Appendix N). Names of participants were recorded in the Patient's Registration List (Appendix O) only for identification to call up patients for post-op questionnaires submission. Patients could decline to answer any questions or withdraw from this study at any time as they wished if they were uncomfortable with the questions, and their participant would be terminated. Patients‘ participation in this study was also terminated if the clinician encountered a recurrent of head and neck cancer lesion, but their post-op oral cancer management will not be affected. Patients who withdrew or refused to participate in this study still proceeded with the consultation session and followed the standard care. However, these patients were replaced in the study by the next eligible patients.

All consented patients were randomised into three study groups of A (PCI-H&N- paper version), B (PCI-H&N- computerised web-based version), and C (normal consultation) by the assistant. Patients assigned to group A and B were required to complete the (i) Sociodemographic information, (ii) PCI-H&N (either in paper or computerised web-based version), and questionnaires comprising (iii) FACT-H&N v4.0 and (iv) Distress Thermometer (DT) in the waiting area/registration counter before the consultation session. Patients could choose (select by ticking _√‘ the box) more than one item of their concerns. Patients in the control group (group C), meanwhile, were only required to complete the (i) Sociodemographic information (ii) FACT-H&N v 4.0 and (iii) DT. Subsequently, a summary sheet of the PCI-H&N paper version and print-out from the computerised version (Appendix P) was attached to patients' dental record to be viewed by the clinicians during the consultation session. The time patient needs to complete the PCI-H&N prompt list was recorded by the assistants for the paper-based version to measure the average time taken to complete the new procedure. If a patient was assisted in completing the PCI-H&N, it was recorded in the form and printed sheet of the web-based version. As for the computerised web-based version, the time was automatically generated once the patient accessed the web and ended upon pressing the ―submission" button. Patients then went through the consultation process. The length of the consultation duration was also recorded by the clinicians or assistants. After the consultation clinic, the PCI-H&N summary sheet and cancer characteristics (Section B of the cover page questionnaire) will be collected by the assistants.

After the consultation session, both the control and new procedure groups were given the satisfaction questionnaire. Additionally, only the new procedure patients (group A and B) were given a feasibility feedback questionnaire. All patients were provided with a set of FACT-H&N and DT questionnaires in a self-addressed stamped envelope with the request to be completed and returned within two to four weeks after the follow-up consultation. The period given was to ensure the possibility of patients' quality of life outcome was evident from the consultation session (Ghoshal, Salins, Deodhar, Damani, & Muckaden, 2016). A monetary token of appreciation for patients' participation in this study was given before they left the clinic.

i) Randomisation

This study applied a randomisation technique by using ping-pong balls. This technique was chosen as the number and time of post-treatment oral cancer patients who turned up for their follow-up appointments were unspecified and to make it easy for the assistants to conduct the study at sites. Therefore, blocked randomisation technique was deemed not to be feasible as it would have added burden to the site assistants. As such, randomisation technique was conducted using a set of three ping-pong balls to allocate patients to the three study groups of A (PCI-H&N paper version), B (PCI-H&N computerised web-based version) and C (normal consultation). The ping-pong balls were labelled and concealed in a container. Patients randomly picked one ping-pong ball that assigned them to one of the study groups. Patients did not know which study groups they were allocated. Once the ping-pong ball had been selected, it will not be placed back in the same container until all the set of three ping-pong balls had been selected. The allocation concealment was ensured by covering the ping-pong balls container with an opaque coloured paper. The dental assistants further instructed the patients to avoid peeking into the container while they picked one ping-pong ball out of the container and gave it to the assistant.

ii) Blinding

Blinding was not applied in this study to either patient or the clinician. The patients could identify the different versions of PCI-H&N, and the clinicians knew which group the patients belonged to from the different format of the paper version and the summary sheet of the computerised web-based version.

3.3.11 Data collection

Phase 1 data collection involved all the three participants (patients, clinicians, and assistants). The data collections are further described in the following section.

i) Patient

Patients‘ baseline data were collected on the day of patient‘s post-treatment review clinic comprising of sociodemographic background and cancer characteristics, PCI-H&N concerns, patient's HRQoL and psychological distress level for the past seven days, patient satisfaction of the follow-up consultation and feasibility of PCI-H&N depending on the patient‘s assigned study group. The data collected from these questionnaires was either self-administered or assisted when required.

Two to four weeks after the review, patients were requested to return a set of questionnaires of FACT-H&Nv4.0 and DT via postal by using a stamped self-addressed envelope (given at the last visit). These were to measure the quality of life and distress level output as results from the consultation session.

ii) Clinicians and dental assistants

Feasibility questionnaires were obtained from the clinicians and dental assistants before the data collection period ended in each OMFS clinic.

3.3.12 Data management and analysis

1) Data management

All collected data were checked for its completeness by the assistants before they sealed the envelope consisting of various completed patient‘s questionnaires. Analyses were carried out using IBM Statistical Package for Social Sciences (SPSS) 20.0. The entered data were checked, and data cleaning was performed by running a simple frequency checking. Eyeballing was performed manually for every block of 10 patients. Missing data of more than 20% were excluded from analysis (Enders, 2003). Some of the variables were re-coded and transformed into new variables. Some were computed to positive statements and given new categorisation for a better presentation of study results.

The variables were grouped and scored as described below:

i) Sociodemographic background

a) Age categorisation

Age was collected as continuous data. However, for analysis, –age” was re-grouped as follows by using the median since the data was skewed: 18-50, 51-65 and 66-100.

b) Ethnicity

Ethnicity was categorised based on the major ethnicity groups in Malaysia namely Malay, Chinese, Indian and Bumiputera of Sabah and Sarawak or others, similar to a previous study among oral cancer survivors (Ghani et al., 2019).

c) Religion

Similarly, religion was also grouped according to the major religious groups in Malaysia, i.e. Muslim, Christian, Buddhist, Hindu, and others.

d) Education level

Categories for the education level is as usually categorised in other studies whereby it was grouped to no formal education, secondary, and tertiary (Hatta et al., 2014).

ii) Cancer characteristics

a) Types of cancer treatment done

The categorisation was followed as recommended by NCCN (2019) and a recent study by Rogers et al. (2019), namely surgery alone, surgery with radiotherapy or chemotherapy, and radiotherapy or chemotherapy without surgery.

b) Duration after treatment completion.

In most studies on cancer survival rate, a 5-year mark was used (Balasundram, Mustafa, Ip, Adnan, & Supramaniam, 2012; Razak, Saddki, Naing, & Abdullah, 2010). Usually, the standard survival years were measured at two years and five years, with a better survival rate at one year. Moreover, since this present study was also assessing the impact on HRQoL and there was a significant finding showing that QoL returns to normal after a year of treatment (Murphy, Ridner, Wells, & Dietrich, 2007), this present study applied the duration as follow: 1 month until 1 year, more than 1 year until 3 years, more than 3 -5 years and >5 years.

iii) Patient Concerns Inventory of Head and Neck (PCI-H&N)

Data were computed into each of the six domains. Patients‘ concerns were combined for a more meaningful data interpretation. The last two general questions were re-coded to denote higher scores as positive output.

iv) Health-related quality of life (HRqoL)

Questions were measured in a 5-point Likert scale. It is a combination of negative and positive statements. Therefore, for easier data analysis, all negative statements were re-coded, and the variables were computed according to the domains. The total score was then grouped into two groups, which were low score: 98 - 164 and high score: 165 – 189, based on the median for categorical analysis and as continuous data of total score FACT-H&N–MAQ, which was calculated using FACT-H&N scoring guideline (Doss et al., 2011).

v) Psychological distress

Distress level was grouped into low level:0-3 and high level: 4-10, according to the accepted cut-off point used in similar PCI-H&N study (Ghazali et al., 2017), and a local study among cancer patients (Yong et al., 2012).

i. Satisfaction with consultation

Satisfaction with consultation was categorised into three groups of ―satisfied” (combining the ―very satisfied” and ―satisfied” score; score 5 to 4), ―neither” (score 3), and ―dissatisfied” (combining the ―dissatisfied” and ―very dissatisfied”; score 2 to 1).

vi) Feasibility of PCI-H&N

Data on the feasibility of PCI-H&N was obtained from the post-treatment oral cancer patients, clinicians, and assistants who were involved in this study. The patients‘ feasibility questions consist of a dichotomous answer of ‗yes‘ and ‗no‘, and the other section of categorical 5-point Likert scale were categorised into three groups of score 5-4, score 3, and score 1-2.

2) Data analysis

All data were checked for normality using the histogram as well as the skewness and kurtosis values, whether the values were within the range of 1.96 until -1.96 (Ghasemi & Zahediasl, 2012). Statistical significance level was established at $p < 0.05$ and the statistical analysis concept of intention-to-treat (ITT) was used in the data analysis.

Data were analysed according to the study groups to compare the significant differences observed. Descriptive analysis was performed for general baseline findings of patients‘ sociodemographic background and cancer characteristics, the selected PCI-H&N items, patient satisfaction with follow-up consultation, and feasibility of PCI-H&N. Descriptive analysis at baseline was meant to enable and allow the analysis of non-respondents after one month of post-consultation.

In Objective 2, the patients‘ HRQoL baseline and psychological distress were analysed for all consented patients. For these outcomes, the comparison was between the PCI-H&N and the control group. The mean and standard deviation were reported for normally distributed data range while the median and inter-quartile range were reported for the skewed data range. Since the data were not normally distributed, a Wilcoxon signed-rank test was performed for continuous outcomes variables of between-group comparison (PCI-H&N and Non-PCI-H&N use).

Categorical data of independent outcome variables were analysed using Chi-square test to assess the association between independent and dependent variables, whereby Fisher exact test for a 2x2 tables and Pearson Chi-square test was used for more than two tables. Categorical data were analysed to compare the distress level (DT) between the two groups of PCI-H&N and control at baseline. Similarly, the selected PCI-H&N items that were selected were also compared in the same manner between the paper version and computerised web-based version. Mann-Whitney test was used in comparing the mean of time taken to complete the PCI-H&N by the patients and the consultation time.

In Objective 4, the association of PCI-H&N number and types of concerns were associated with patients‘ sociodemographic and cancer characteristic profiles by using Pearson chi-square statistical test. In this analysis, the number of PCI-H&N items was grouped into the low number (0-3) and high number (4-17) of concerns selected. The grouping was chosen based on the median items selected.

Similarly, the association of number and types of PCI-H&N (items and domains) were performed by using Pearson chi-square statistical test. Further analyses were conducted using Spearman-Ho correlation and linear regression for continuous variables to determine the factor association between PCI-H&N and HRQoL. For categorical variables, logistic regression was used to determine the factor association between PCI-H&N and psychological distress and satisfaction.

The median change between pre- and post-follow-up consultation session within the PCI-H&N user groups, and between PCI-H&N and non-PCI-H&N user group were measured, with ‗+' median scores showing improvement in patients' quality of life. The comparative analysis was conducted using Paired t-test, Wilcoxon test, Mann-Whitney test and McNemar test as appropriate.

3.3.13 Data protection

The privacy of all participants and their personal data information were protected. Patients were identified only by their identification number (ID) and by their hospital's registration number on the questionnaires given. Patients' names and contact details were recorded in the Patients' Registration List for phone call reminders by the assistants for the return of post-treatment questionnaires within 2-4 weeks after the visit. The post-op questionnaires were also identified by patients' personalised ID and hospital registration's number.

The computerised web-based version could only be accessed by the clinicians and assistants to allow the PCI-H&N to be used by the patients and to print out the summary sheets. However, they were not permitted to retrieve the patients' data. It could only be accessed by the principal researcher by using the researcher personal log in ID address.

All the completed questionnaires were sealed in individual envelopes and collected by the assistant before patients left the clinic. It was kept in a locked cabinet in the clinic until the data collection period ended. Once completed, the researcher collected the records from all the six centres and kept them in a locked cabinet in the department. The data will be destroyed as recommended by National Archive after 24 months upon completion of the study.

3.4 Phase 2 study (Qualitative)

3.4.1 Study design

Phase 2 study was a qualitative descriptive study design conducted among the health personnel involved and was adopted to explore the feasibility of PCI-H&N used during the follow-up consultation. This phase specifically aimed to describe the participants‘ experiences and the opportunities for its implementation.

A few other available frameworks that had been used in other studies include RE-AIMED (Glasgow, Vogt, & Boles, 1999) and A-toolbox for health intervention evaluation (Smith, Morrow, & Ross, 2015). However, the present study adopted a more constructive framework known as FRAME-IT (Gonot-Schoupinsky & Garip, 2019), as it seemed to be more appropriate for evaluating intervention at an early stage. The list of questions was designed according to the framework (FRAME-IT) and was guided by a comprehensive review of the literature (Glasgow et al., 1999; Gonot-Schoupinsky & Garip, 2019) and the researcher‘s knowledge to suit the local settings in Malaysia. FRAME-IT comprises of seven domains, i.e. F: Feasibility, R: Reach-out, A: Acceptability, M: Maintenance, E: Efficacy, I: Implementation and T: Tailorability. Table 3.5 shows the list of structured questions. The guided, structured interview consisted of open-ended questions that were designed based on the evaluation framework with a list of questions prompts for each of the main open-ended questions. This design was to ensure consistency of data collected at multi-centres.

3.4.2 Study population sample

The sampling frame was among all the health personnel (clinicians and the dental assistants) involved in the conduct of the present study. A total of 11 clinicians and five assistants were interviewed at individual sites. All involved were from various demographic and working experiences. A purposive sampling method was applied. This study was conducted only among the selected health personnel selected in the data collection so that the information gathered would be valuable and meaningful.

3.4.3 Pre-testing

The draft of the interview guided questions were pilot-tested with two dental colleagues who fulfilled the similar inclusion study criteria, as mentioned in section 3.2.4, for the clinicians. The pre-testing was to ensure clarity of the questions, and the interpretation and answers that reflected the intentional, specific domains of the framework. Besides that, it was also to estimate the length of the interview approximately.

Table 3.5: Structured key questions based on FRAME-IT dimensions

DIMENSIONS	KEY CONCERNS	KEY QUESTIONS
Feasibility	Practical concerns whether the intervention can work as intended	i) Functionality: the use of prompt list during follow-up consultation. ii) Technicality: paper vs web-based versions
Reach-out	Demographic and health profile of the intended population	i) Was the prompt list able to be used by all post-treatment oral cancer patients? ii) What about the clinicians and assistant? Is this intervention was exposed to all of them?
Acceptability	Appropriateness	i) Is it acceptable? ii) How do you find the intervention?
Maintenance	Fidelity (whether intervention content is being used as instructed) and usage behaviour (how intervention content is being used, and what works and does not)	i) Was the workflow as intended by the protocol? ii) Usage behaviour: a) Patients -Ability to self-administer or be assisted? -Background majority of patients b) Clinicians -Do you see it being adopted during the post-treatment follow-up patients? c) Assistants -How the assistants find the intervention? Burdensome? E.g. to approach patients, conduct the prompt list, follow-up calls -Was the intervention a misplace of resources? Need additional staff to conduct the prompt list? iii) Can it sustain? iv) What are the supports required for its sustainability -Infrastructure/fundings?

Table 3.5: Structured key questions based on FRAME-IT dimensions (continued)

DIMENSIONS	KEY CONCERNS	KEY QUESTIONS
Efficacy	Benefits of the intervention	i) Produce intended immediate outcomes? Benefit? Unanticipated effects & risks? ii) As an organisation, will we add value to our service by offering this prompt list? iii) Outcomes: A) Behavioural outcomes (a) Patients: -Do you think the prompt list encourages patients to share their concerns and be more openly? -Were there changes in patients' concerns? Issues raised during the follow-up consultation? (b) Clinicians: - What do you think about the prompt list? Can it help to improve the follow-up consultation? - How do you see the usefulness of the prompt list? To use as routine? Compared to the current procedure? -Were there changes in the follow-up consultation issues? Compared to current practice e.g. clinicians need to prompt questions? B) Participants-centred QoL perspectives -What are the most important outcomes you expected to see? e.g. Patients satisfaction, willingness to use the prompt list

Table 3.5: Structured key questions based on FRAME-IT dimensions (continued)

DIMENSIONS	KEY CONCERNS	KEY QUESTIONS
Implementation	Delivery of the intervention Challenges, training, technology involved	i) Does our organisation have the capacity, resources, or expertise necessary to deliver the program? ii) Environment? What need to be considered? a) Physical support -Requirements of the software or hardware -Internet support availability b) Technology/system support -Hospital current patient system management -Possibility of integrating into the system c) Human support -The needs of additional staff (possibility for contract staff) to conduct the PCI at the registration counter -To conduct training
Tailorability	Customise	Refine and adapt the intervention a) How can it be improved? How to fit into your setting? b) Do the clinical setting factors have the potential to influence delivery? Environment? c) Do you encounter any barriers during the study? What is needed more?

3.4.4 Conduct of study

Written informed consent (Appendix Q) was obtained from the participants on the permission for participating in the interview and permission for the audio recording. Participation in this study was voluntary and not mandatory. They were briefed on the purpose of the interview.

The FGD was carried out by the principal researcher. The session was digitally recorded using a voice recorder application from an android hand phone to capture the participant‘s own words aiding in a detailed analysis, and the discussion was conducted in a room. They were interviewed on the resources‘ availability and the feasibility of PCI-H&N to be integrated as a routine procedure during the follow-up consultation. The information was documented digitally and physically on paper. Observations were also noted by the researcher to document items of non-verbal information such as participants‘ gestures, expressions, and other relevant observations. The interviews were guided by open-ended questions. The primary purpose of the interviews was to obtain insight from the implementers of PCI-H&N.

A welcoming statement started the session, and the data was collected through a structured FGD. The questions were not in the same sequence as listed. The session lasted approximately 30 minutes which was guided by the list of questions prepared. Each of the participants took turns to contribute their inputs, and the researcher concluded by summarising all inputs at the end of the interview sessions.

3.4.5 Data management and analysis

Manual transcribing and data analyses were conducted without using any qualitative software programme. The recorded interviews were transcribed and then analysed using a thematic analysis technique of FRAME-IT domains. It was then verified by an independent researcher to ensure trustworthiness. In the thematic analysis, the first step of analysing was forming the coding followed by classifying the themes from the data set of the interviews. Since the interviews were conducted more than once, the items in each transcript were then compared. Then the data were categorised into several emerging themes that arose from readings of the transcribed data.

No triangulation was conducted as the purpose of conducting the interviews were to obtain the implementers‘ insights and to report the findings. A triangulation process was to increase the robustness of the study and to minimise the level of biases that may arise from the researcher. Therefore, to enhance study rigour, verbatim quotes were used when reporting on the result‘s findings which provide evidence to support the researcher‘s explanation of the data. In the present study, the themes were generated from the FRAME-IT domains.

3.4.6 Data protection

All data collected from the interviews and the transcripts were guaranteed its safety whereby after the audio recordings were transcribed; they were then stored in the researcher‘s personal email drive. This step was to ensure that only the researcher could access it. The data in the recorder was then deleted. Participants‘ names were not mentioned in the study results and discussions. Collected data on the transcribed and the soft copy of the audios will be destroyed as recommended by National Archive after 24 months upon completion of the study.

3.5 Ethical approval

This study has obtained ethical approval from the Medical Ethics Committee Faculty of Dentistry, University Malaya (DF CO1901/0001 P), and an approval to conduct the study in MOH dental facilities from the Oral Health Division of MOH, Malaysia (KKM-600-56/7/2 Jld 4-29). Prior to the conduct of this study, NMRR ethical approval was also obtained from NMRR, ID: NMRR-18-3624-45010 (IIR).

3.6 Funding

This study did not receive any funding.

CHAPTER 4: RESULTS

4.1 Response rate

All patients who turned-up on their follow-up consultation and fulfilled the inclusion and exclusion criteria were recruited for this study. The estimated sample size required for this study was 192 with 64 patients in each arm. However, during the data collection period (April – December 2019) the response rate achieved was as tabulated in Table 4.1. Neither of the study groups reached the estimated number required.

Table 4.1: Response rate of the sample by group (n=123)

No	Hospitals	PCI-H&N Paper version (n,%)	PCI-H&N Computerised web-based version (n,%)	Control (n,%)	Total patients
1	Kuala Lumpur Hospital, FTKL	7(8.2)	5(4.1)	7(5.7)	19(15.4)
2	Seberang Jaya Hospital, Penang	3(2.4)	5(4.1)	8(6.5)	16(13.0)
3	Sultanah Aminah Hospital, Johor	5(4.1)	5(4.1)	5(4.1)	15(12.2)
4	Queen Elizabeth Hospital, Sabah	15(12.2)	6(4.9)	7(5.7)	28(22.8)
5	Sarawak General Hospital, Sarawak	6(4.9)	5(4.1)	6(4.9)	17(13.8)
6	OMFS, Faculty of Dentistry, UM	19(15.4)	4(3.3)	5(4.1)	28(22.8)
	Total	55(44.7)	30(24.4)	38(30.9)	123(100)

The overall response rate (consented patients who were presented on appointment day and were eligible for recruitment) was 87.9%; 123 participants consented and agreed to participate in this study. Of these participants, 55 (44.7%)

patients for the paper version, 30 (24.4%) patients for the computerised web-based version and 38 (30.9%) patients in the control groups. Of the 123 participated patients, 78 (63.4%) patients completed and returned the questionnaires via postal route. Figure 4.1 shows the summary of the study groups and patients involved in this study.

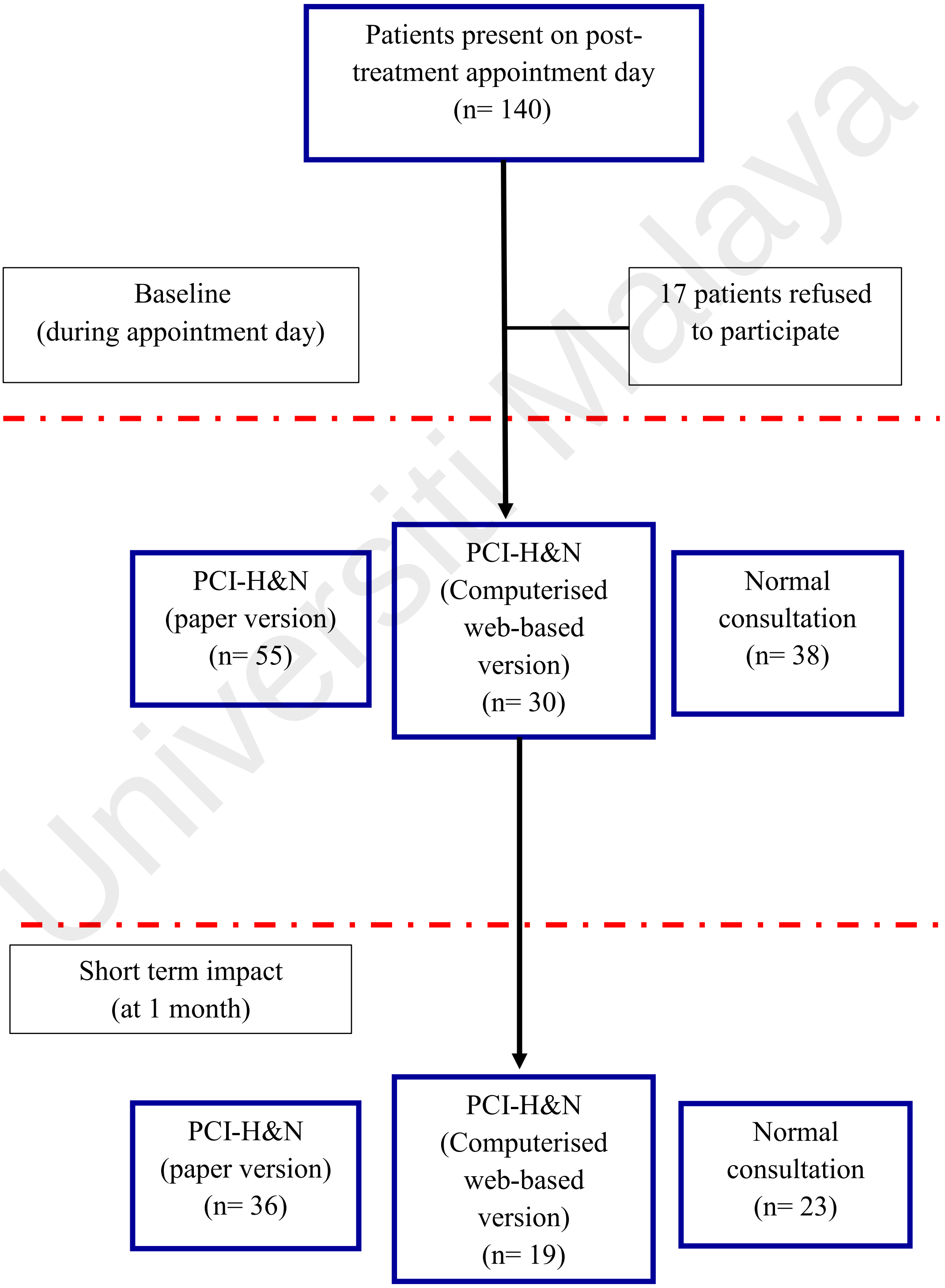


Figure 4.1: Summary of participants at baseline and 1 month after.

4.2 Sociodemographic background

Table 4.2 shows the socio-demographic profiles in the PCI-H&N groups and the control group at baseline. Females predominated in this study with almost 60% (59.3%) and the proportion among study groups were almost equal at baseline. As for the computerised web-based study group, the proportion between male and female were equally distributed. Most of the patients were among 51-65 years old age group (41.5%) with a mean age of 61 years (SD=12.5) and age range was 22 – 81 years old.

With regards to ethnicity, participants were mainly Malays (36.6%) and Chinese (31.7%), while 11.4% were Indians and 20.3% were Bumiputeras/ others which comprised indigenous ethnicity from Sabah and Sarawak. Malays constituted almost 50% (46.7%) in the paper version of PCI-H&N while Chinese constituted 41.0% in the control group. More than half of the patients are currently married (68.3%) and since majority of patients were among Malays (36.6%), therefore Muslims contributed the most at baseline. Majority of the patients received up to secondary (41.5%) and tertiary education level (45.5%) and only 13.0% did not receive any formal education which were mainly in the paper version.

Table 4.2: Patients' sociodemographic background (n=123)

Variables		Total (n=123,%)	Paper version (n=55, %)	Computerised web-based version (n=30; %)	Control (n=38;%)	X^2	p-value
Gender	Male	50 (40.7)	18 (36.0)	15 (30.0)	17 (34.0)	2.781	0.249
	Female	73 (59.3)	37 (50.7)	15 (20.5)	21 (28.8)		
Age	Mean (SD)	60.1 (12.5)	60.5(12.4)	55.9(13.1)	62.8(11.6)	2.679^{+}	0.073
	Range (year old)	22-81					
	18-50	30 (24.4)	13 (43.3)	10 (33.3)	7 (23.3)	3.031	0.553
	51-65	51(41.5)	22 (43.1)	13 (25.5)	16 (31.4)		
	66-100	42 (34.1)	20 (47.6)	7 (16.7)	15 (35.7)		
Ethnicity	Malay	45 (36.6)	21 (46.7)	15 (33.3)	9 (20.0)	8.908	0.205^
	Chinese	39 (31.7)	15 (38.5)	8 (20.5)	16 (41.0)		
	Indian	14 (11.4)	5 (35.7)	2 (14.3)	7 (50.0)		
	Bumiputera of Sabah/Sarawak/ others	25 (20.3)	14 (56.0)	5 (20.0)	6 (24.0)		
Marital status	Married	84 (68.3)	37 (44.0)	21 (25.0)	26 (31.0)	3.368	0.515^
	Unmarried Single	19 (15.5)	6 (31.6)	6 (31.6)	7 (36.8)		
	Divorcee/ Widow	20 (16.2)	12 (60.0)	3 (15.0)	5 (25.0)		

Statistical test: Pearson Chi-square; Fisher Exact test ^, One way ANOVA test^{+}

Table 4.2: Patients‘ sociodemographic profile (n=123) (continued)

Variables		Total (n=123,%)	Paper version (n=55, %)	Computerised web-based version (n=30; %)	Control (n=38;%)	X^2	p-value
Religion	Muslim	49 (39.8)	23 (46.9)	15 (30.6)	11 (22.4)	8.611	0.340^
	Christian	30 (24.4)	16 (53.3)	6 (20.0)	8 (26.7)		
	Buddhist	26 (21.1)	8 (30.8)	7 (26.9)	11 (42.3)		
	Hindu	14 (11.4)	6 (42.9)	1 (7.1)	7 (50.0)		
	Others	4 (3.3)	2 (50.0)	1 (25.0)	1 (25.0)		
Education level	No formal education	16 (13.0)	9 (56.3)	3 (18.7)	4 (25.0)	8.010	0.093^
	Secondary	51 (41.5)	16 (31.4)	13 (25.5)	22 (43.1)		
	Tertiary	56 (45.5)	30 (53.6)	14 (25.0)	12 (21.4)		

Statistical test: Pearson Chi-square; Fisher Exact test ^, One way ANOVA test

4.3 Cancer characteristic

Table 4.3 shows cancer characteristic of patients involved. Ten cancer sites presented in this study. Approximately half of the patients had cancer of the tongue (n=66; 53.7%) and salivary gland (0.8%) was least reported. Besides tongue, buccal mucosa and lips were also highly reported with 18.7% and 8.9% respectively. Majority of the patients were diagnosed at an early cancer stage with 41.5% at stage 1, 26.8% at stage 2, and followed by stage 4 (17.1%) and stage 3 (14.6%).All patients recruited in this study were among those who had completed their treatment and were at review phase at least from one month after completion of the treatment.

Most of the patients had undergone surgery treatment only (n=61, 49.6%), radiotherapy/ chemotherapy without surgery (n=2, 1.6%) and combination of surgery with/ without radiotherapy and chemotherapy (n=60, 48.8%). Median time after completion of the treatment was 2 years (IQR=1.0-4.0) with a range of less than a year to 15 years survival.

Table 4.3: Patients' cancer characteristics (n=123)

Variables		Total (n=) %	Paper version (n=55; %)	Computerised web-based version (n=30; %)	Control (n= 38; %)	X^2	p-value
Tumour site	Lips	11(8.9)	5(45.5)	2(18.2)	4(36.4)	0.309	0.923^
	Buccal	23(18.7)	6(26.1)	6(26.1)	11(47.8)	4.854	0.088
	Alveolus	6(4.9)	3(50.0)	1(16.7)	2(33.3)	0.206	1.000^
	Gingivae	2(1.6)	1(50.0)	0	1(50.0)	0.749	1.000^
	Tongue	66(53.7)	32(48.5)	17(25.8)	17(25.8)	1.778	0.411
	Salivary gland	1(0.8)	0	0	1(100.0)	2.255	0.553^
	Mandible	9(7.3)	5(55.6)	4(44.4)	0	4.856	0.053^
	Maxillary	3(2.4)	1(33.3)	1(33.3)	1(33.3)	0.196	1.000^
	Palate	6(4.9)	2(33.3)	0	4(66.7)	4.334	0.139^
	Floor of the mouth	2(1.6)	0	0	2(100.0)	4.548	0.152^
TNM staging	I	51(41.5)	22(43.1)	10(19.6)	19(37.3)	9.057	0.193^
	II	33(26.8)	20(60.6)	5(15.2)	8(24.2)		
	III	18(14.6)	6(33.3)	7(38.9)	5(27.8)		
	IV	21(17.1)	7(33.3)	8(38.1)	6(28.6)		
Cancer treatment done	Surgery only	61(49.6)	29(47.5)	10(16.4)	22(36.1)	4.437	0.109
	Radiotherapy/ Chemotherapy without surgery	2(1.6)	0	1(50.0)	1(50.0)	1.696	0.304^
	Surgery & radiotherapy/ & chemotherapy	60(48.8)	26(43.3)	19(31.7)	15(25.0)	3.910	0.142

Statistical test: Pearson Chi-square; Fisher Exact test ^; Kruskal- Wallis test^{+}

Table 4.3: Patients‘ cancer characteristics (n=123) (continued)

Variables		Total (n=) %	Paper version (n=55; %)	Computerised web-based version (n=30; %)	Control (n= 38; %)	X^2	p-value
Duration after treatment completion (n=98)	1 month till 1 year	26(21.1)	11(42.2)	8(30.8)	7(27.0)	3.850	0.697
	>1 year till 3 years	41(33.3)	19(46.3)	9(22.0)	13(31.7)		
	>3years till 5 years	12(9.8)	7(58.3)	1(8.3)	4(33.3)		
	>5 years	19(15.4)	6(31.6)	6(31.6)	7(36.8)		
	Median (IQR)	2.0yrs (1.0 -4.0)	2.0 yrs (1.0 -4.0)	2.0 yrs (1.0-5.75)	2.0yrs (2.0-5.0)	0.686	0.710^{+}
	Range			$\geq$ 1 month – 15 years			

Statistical test: Pearson Chi-square; Fisher Exact test ^; Kruskal- Wallis test^{+}

4.4 Post-treatment oral cancer patient concerns by using PCI-H&N during follow-up consultation.

The PCI-H&N prompt list consists of seven domains and one free text for additional comment. Generally, the physical status (n=59) and emotional status were the main domains highlighted by patients in all study groups (Table 4.4). Table 4.5 shows the individuals items selected by each PCI-H&N study groups. Patients may chose more than one items.

Based on the Pearson Chi-square test, few concerns which showed significant association with the version of PCI-H&N filled were dry mouth (p-value=0.043), taste (p-value= 0.0001), coughing (p-value=0.048), and coping ability (p-value=0.041). Three of these significant items (coughing, dry mouth and taste) were categorised under physical status domain.

Table 4.4: Number of patients selected items from PCI-H&N domain (n=85)

	PCI-H&N domain						
	Phy (n)	Emo (n)	Tx (n)	Personal (n)	Social (n)	Econ (n)	Spirit (n)
Number of patients	59	6	23	22	7	6	1

- Patients may choose more than one concerns within the domains.

Phy: Physical status; Emo: Emotional status; Tx: Treatment-related; Personal: Personal function; Social: Social care & social well-being; Econ: Economic status; Spirit: Spiritual well-being

Table 4.5: Ranking of items within domains of patients' concerns for the past 7 days (n= 85).

Variables	Items	Total	Version of PCI-H&N		P-value
			Paper version (n=55; 64.7%)	Computerised web-based (n=30; 35.3%)	
Physical status	Dental health/teeth	21 (24.7)	17 (20.0)	4(4.7)	0.073^
	Chewing/eating	18 (21.2)	10(11.8)	8(9.4)	0.360^
	Dry mouth	18 (21.2)	8(9.4)	10(11.8)	**0.043*^**
	Sore mouth	14 (16.5)	11(12.9)	3(3.5)	0.360
	Swallowing	13 (15.3)	7(8.2)	6(7.1)	0.529
	Shoulder	11 (12.9)	7(8.2)	4(4.7)	1.000^
	Speech/ voice	10 (11.8)	6(7.1)	4(4.7)	0.740
	Pain in the head & neck	9 (10.6)	7(8.2)	2(2.4)	0.483
	Taste	9 (10.6)	1(1.2)	8(9.4)	**0.001***
	Sleep	9 (10.6)	5(5.9)	4(4.7)	0.714
	Swelling	8 (9.4)	6(7.1)	2(2.4)	0.707
	Mouth opening	7 (8.2)	3(3.5)	4(4.7)	0.237^
	Coughing	7 (8.2)	7(8.2)	0	**0.048***
	Weight	7 (8.2)	6(7.1)	1(1.2)	0.413
	Appetite	6 (7.1)	3(3.5)	3(3.5)	0.661
	Fatigue/tiredness	5 (5.9)	2(2.4)	3(3.5)	0.340
	Indigestion/ constipation	5 (5.9)	4(4.7)	1(1.2)	0.652
	Hair loss	4 (4.7)	2(2.4)	2(2.4)	0.611
	Hearing	4 (4.7)	1(1.2)	3(3.5)	0.124
	Pain elsewhere	3 (3.5)	1(1.2)	2(2.4)	0.283
	Breathing	2 (2.4)	1 (1.2)	1(1.2)	1.000
	Nausea	2 (2.4)	1(1.2)	1(1.2)	1.000
	Smell	2 (2.4)	2(2.4)	0	0.538
	Vomiting/sickness	1 (1.2)	0	1(1.2)	0.353
Personal function	Recreation (eg sports, gardening)	7 (8.2)	2 (2.4)	5 (5.9)	0.091
	Ability to work/ daily activity	5 (5.9)	2 (2.4)	3 (3.5)	0.340
	Memory	5 (5.9)	2 (2.4)	0	0.538
	Appearance/looks	4 (4.7)	2 (2.4)	2 (2.4)	0.611
	Mobility (able to move about)	4 (4.7)	2 (2.4)	2 (2.4)	0.611

Statistical test: All Fisher's Exact test except for Pearson Chi-square^; *p<0.05.

Table 4.5: Ranking of items within domains of patients‘ concerns for the past 7 days (n= 85) (continued)

Domains	Items	Total	Version of PCI-H&N Paper version (n= 55 ; %)	 Computerised web-based (n= 30 ; %)	p-value
Treatment related	Cancer treatment	12 (14.1)	8 (9.4)	4 (4.7)	1.000
	Diet restriction	11 (12.9)	5(5.9)	6(7.1)	0.184
	Health supplement/diet	6(7.1)	3(3.5)	3(3.5)	0.661
	Wound healing	4 (4.7)	3 (3.5)	1(1.2)	1.000
	Regret about treatment	2 (2.4)	2 (2.4)	0	0.538
	PEG tube	0	0	0	0
Social care & social well-being	Support from my family	3(3.5)	1(1.2)	2(2.4)	0.247
	Dependents/children	2(2.4)	1(1.2)	1(1.2)	1.000
	Home care/district nurse	2(2.4)	1(1.2)	1(1.2)	0.660
	Carers	1(1.2)	1(1.2)	0	1.000
	Relationships	1(1.2)	1(1.2)	0	1.000
	Sexuality /Intimacy	0	0	0	0
	Lifestyle issues (eg smoking/alcohol)	0	0	0	0
Economic status	Financial help	6(7.1)	2(2.4)	4(4.7)	0.179
Emotional status	Recurrence/ Fear of the cancer coming back	27 (31.8)	14 (16.5)	13 (15.3)	0.091^
	Fear of the adverse events	10(11.8)	5(5.9)	5(5.9)	0.314
	Anxiety/worry/tension	5 (5.9)	5(5.9)	0	0.156
	Depression/ sadness	4(4.7)	3(3.5)	1(1.2)	1.000
	Angry/ Frustrated	3(3.5)	2(2.4)	1(1.2)	1.000
	Coping	3(3.5)	0	3(3.5)	**0.041***
	Self-esteem	2(2.4)	2(2.4)	0	0.538
	Mood swings	1(1.2)	1(1.2)	0	1.000
Spiritual well-being	Spiritual/religious aspects	1(1.2)	1(1.2)	0	1.000

Statistical test: All Fisher‘s Exact test except for Pearson Chi-square^; *p<0.05.

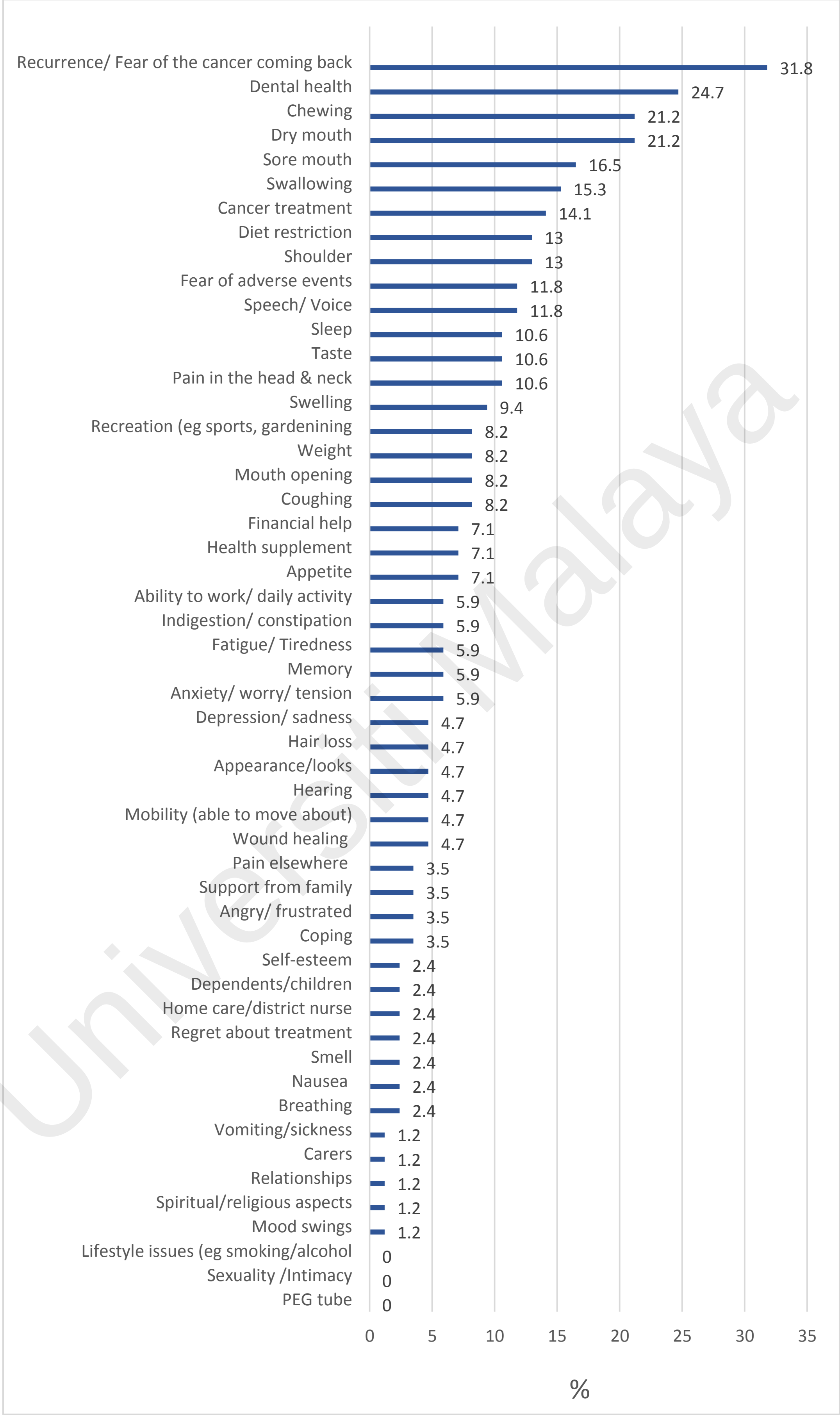


Figure 4.2: Overall number of concerns among the post-treatment oral cancer patients for the past 7 days (n=85)

Figure 4.2, summarised the items listed with the most frequently selected by the patients in descending order were ‗fear of cancer coming back' (n=27, 31.8%), issues on their ‗dental or teeth problem' (n=21, 24.7%), ‗chewing' (n=18, 21.2%)), ‗dry mouth' (n=18, 21.2) and ‗sore mouth' (n=14, 16.5%). From the 52 listed item, three items were not selected by any of the patients were namely ‗PEG tube', ‗sexuality/ intimacy', and ‗lifestyles'. There were lesser concerns observed among issues of social care and social well-being, and also spiritual well-being. The numbers of PCI-H&N items selected was median 3 (IQR=1-5.5) and varied between 0-17 items. This study showed that 23.5% of the patients did not select any items, 33% selected one to three items, and 43.5% selected four or more concerns.

Most of the patients (n=54) chose to be assisted either by their family member or by the dental assistant in filling the PCI-H&N prompt list. A small proportion (n=8) were able to complete the computerised web-based version by themselves (Table 4.6).

Table 4.6: Patients' preference to be assisted in completing PCI-H&N (n=85).

	Require assistant	No assistant needed	Total	p-value
Paper version	32 (58.2)	23 (41.8)	55 (100)	0.165
Computerised web-based	22 (73.3)	8 (26.7)	30 (100)	

Statistical test: Pearson Chi-square

a. 0 cells (0.0%) have expected count less than 5. The minimum expected count is 10.94.

4.5 Post-treatment oral cancer patient health- related quality of life and psychological distress level during the follow-up consultation.

Table 4.7 shows six domains in FACT-H&Nv4.0 and the total score of FACT-H&N-MAQ. Median values for both groups showed similarity for all domains. Ordinal data was recoded to positive statements whereby higher scores showed better HRQoL. Based on Mann-Whitney test, there were no significant associations between the HRQoL domains and the study groups at baseline. Overall, both PCI-H&N and control groups showed homogenous data at baseline. The total scores of each domains showed on the higher range except the HNS total score which slightly lower than its range.

Table 4.7: Baseline level of health- related quality of life domains among post-treatment oral cancer patients for the past seven days (n= 123).

Domains	Range	PCI-H&N (n= 85) median(IQR)	CONTROL (n= 38) median (IQR)	p-value
Physical well-being	0-28	27.0 (4.00)	27.0 (5.25)	0.898
Social well-being	0-24	22.0 (6.00)	22.0 (6.00)	0.935
Emotional well-being	0-24	22.0 (4.50)	22.0 (7.00)	0.714
Functional well-being	0-28	25.0 (7.50)	26.0 (6.00)	0.436
Head& Neck subscale	0-36	26.0 (9.5)	25.0 (9.00)	0.724
Malaysian-added questions	0-28	25.0 (6.00)	25.0 (7.00)	0.445
FACT-HN-MAQ	0-168	139.0 (26.5)	140.0 (27.25)	0.950

Statistical test: Mann-Whitney T-test

Table 4.8 shows the general HRQoL experienced by the patients for the past seven days and from the last dental visits. Overall, at baseline both PCI-H&N and control groups showed good and improved HRQoL. Pearson Chi-square showed p-value more than 0.05 with no associations between the measured general HRQoL for both study groups. The minimum expected count is less than 1 thus the results are not conclusive.

Table 4.8: Baseline of health- related quality of life among post-treatment oral cancer patients for the past seven days and from the last dental visit (n= 123).

	HRQoL for the past 7 days					HRQoL from the last dental visits				
	Good (n; %)	Average (n; %)	Poor (n; %)	Total (n; %)	p-value (a)	Improved (n; %)	Same (n; %)	Worse (n; %)	Total (n; %)	p-value (b)
PCI-H&N group	63 (74.1)	19 (22.4)	3 (3.5)	85 (100)	0.71	49 (57.6)	35 (41.2)	1 (1.2)	85 (100)	0.89
Control group	30 (78.9)	8 (21.1)	0 (0)	38 (100)		23 (60.5)	15 (39.5)	0 0	38 (100)	

Statistical test: Fisher‘s Exact test

a. 2 cells (33.3%) have expected count less than 5. The minimum expected count is .93.
b. 2 cells (33.3%) have expected count less than 5. The minimum expected count is .31.

*Good: very good/ good ; *poor: poor/ very poor *Improve: much improved/ little improved; *same: the same, *worse: little worst/much worst

A Pearson‘s chi-square was used to assess baseline levels of psychological distress (DT) level among study groups (Figure 4.3). The chi-square test was statistically non-significant, X^2 (1, n=123) = 0.485; p-value=0.486 with 0 cells (0.0%) have expected count less than 5 (the minimum expected count is 7.41). Therefore, it met the assumption. Approximately 80% of the patients in this study group had low levels of DT (PCI-H&N group: 54.5%; control group: 26.0%). The remaining of the study group (19.5%) reported to had higher level of DT. The range of DT level among patients involved in this study group was 0 until 10 with one patient claimed to have stress at level 10.

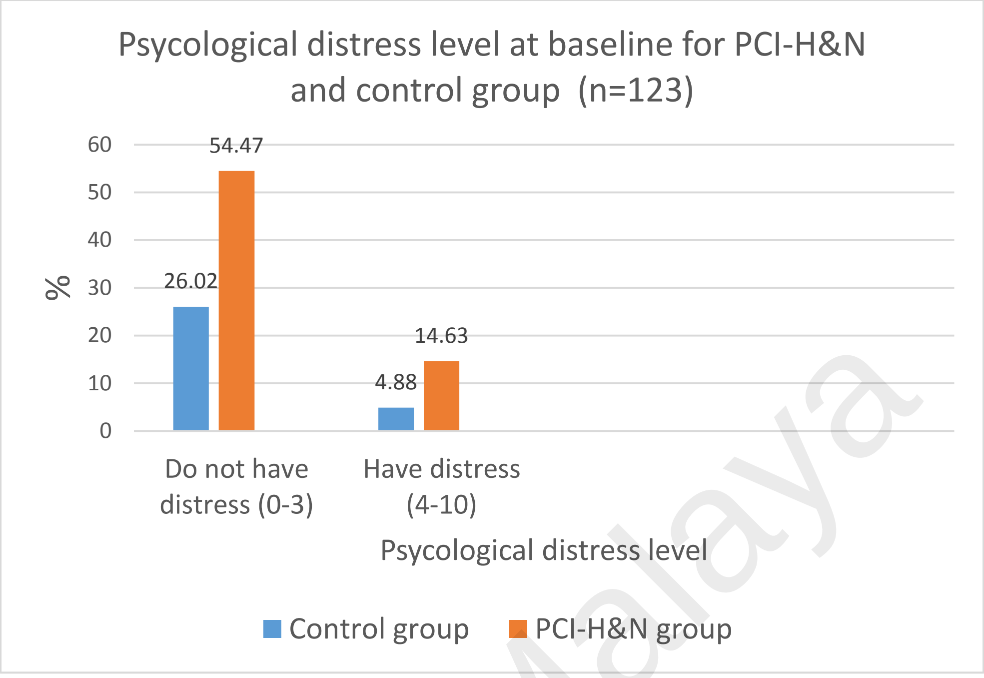


Figure 4.3: Baseline of psychological distress level among post-treatment oral cancer patients for the past 7 days (n= 123)

The psychological distress questionnaire comprised of five domains of listed problems possibly encountered by post-treatment oral cancer patients which they perceived as sources of their psychological distress. As shown in Table 4.9, no significant difference was observed among the psychological distress problems domains. Findings showed physical and emotional domains were higher proportion reported compared to other domains. Only 1.2 % among the control group has reported on spiritual or religious concerns.

Table 4.9: Baseline of problems encountered by post-treatment oral cancer patients for the past 7 days that were related to psychological distress (n=123)

	Post-treatment psychological distress problems				
	Physical	Emotional	Practical	Family	Spiritual/ religious
PCI-H&N (n= 85,%)	31 (36.5)	30 (35.3)	18 (21.2)	11 (12.9)	0 (0)
Control (n= 38, %)	12 (31.6)	10 (26.3)	7 (18.4)	1 (2.6)	1 (2.6)
p-value	0.599	0.326	0.726	0.102^	0.309^

Statistical test: Pearson Chi-square, Fisher Exact test^.

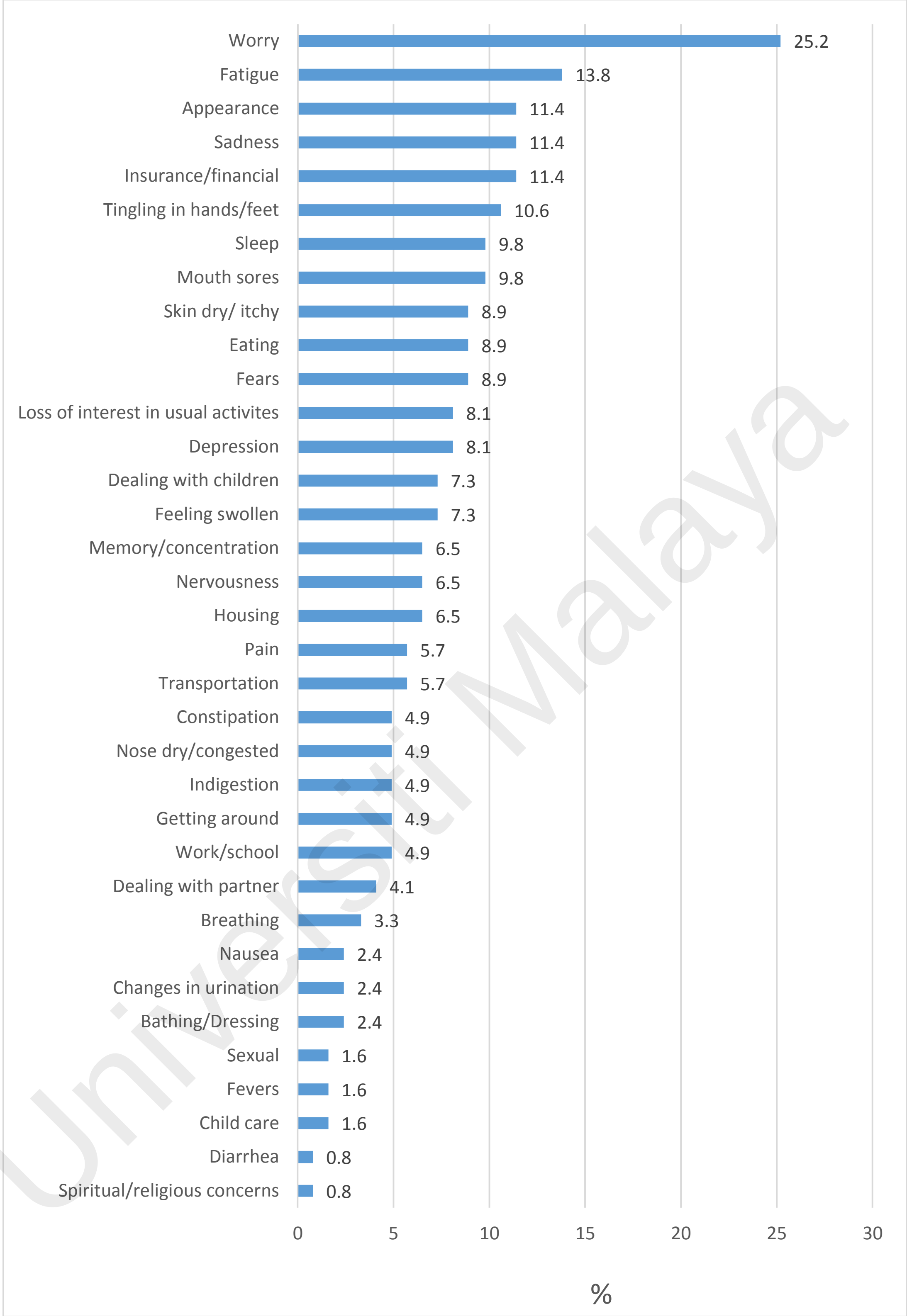


Figure 4.4: Specific problems encountered by post-treatment oral cancer patients for the past 7 days that were related with psychological distress (n= 123).

Figure 4.4 shows the specific problems that they encountered for the past seven days. Of the listed items, 25.2% of patients experienced ‗worry‘ followed by ‗fatigue (13.8%), appearance (11.4%), sadness (11.4%), and insurance/ financial problems (11.4%). Least in the listed problems were spiritual/ religious concerns (0.8%) and diarrhoea (0.8%).

Table 4.10 shows the outcome of HRQoL by domains and total score for the PCI-H&N and control study groups at baseline and at 1 month after. There was no significant median difference in both study groups. Generally, the analysis revealed almost similar (homogenous) HRQoL outcomes for the study groups at baseline.

At one month after (post-consultation), there were slight non-significant differences in mean between the PCI-H&N and control groups whereby higher mean were noticeable among the PCI-H&N group except for emotional status and personal function domains that showed no changes in the median. As for MAQ, there was a slight increment of median at one month post-consultation (median: 28.0; IQR=24.0-30.0) compared to median at baseline (median: 25.0; IQR: 21.0-27.0).

Table 4.10: Outcome of HRQoL (domains and total score) by study groups (n=78)

	Pre-consultation (Baseline)			Post-consultation (1 month)		
Domain	PCI-H&N (n= 55), median(IQR)	Control (n= 23), median(IQR)	p-value	PCI-H&N (n= 55), median(IQR)	Control (n= 23), median(IQR)	p-value
PWB	27.0(24.0-28.0)	28.0(24.0-28.0)	0.493	26.0(21.0-28.0)	25.0(21.0-27.0)	0.290
SWB	22.0(19.0-24.0)	24.0(18.0-24.0)	0.753	19.0(17.0-23.0)	18.0(15.0-22.0)	0.651
EWB	22.0(20.0-23.0)	22.0(20.0-24.0)	0.925	20.0(17.0-22.0)	20.0(14.8-23.0)	0.586
FWB	27.0(21.0-28.0)	26.0(23.0-28.0)	0.413	21.0(18.0-25.0)	21.0(16.0-23.0)	0.563
HNS	26.0(22.0-31.0)	25.0(21..0-29.0)	0.629	26.0(17.0-29.0)	22.0(15.0-25.0)	0.104
MAQ	25.0(21.0-27.0)	25.0(21.0-27.0)	0.982	28.0(24.0-30.0)	26.0(22.0-28.5)	0.158
FACT-HN-MAQ	147.0(128.0-156.0)	144.0(125.0-157.0)	0.895	135.5(112.8-148.3)	126.5(119.5-1134.5)	0.298

Statistical test: Mann- Whitney test

*PWB: physical well-being, SWB: social well-being, EWB: emotional well-being, FWB: functional well-being, HNS: Head & Neck Subscale, MAQ: Malaysian –added questions

Table 4.11: Patients' perceive on HRQoL for the past 7 days and from the last follow-up date at baseline (n=78).

	HRQoL for the past 7 days					HRQoL from the last dental visits				
	Very good/ Good (n; %)	Average (n; %)	Poor/ Very poor (n; %)	Total (n; %)	p-value	Much improved/ A little improved (n; %)	The same (n; %)	A little worse/ Much worse (n; %)	Total (n; %)	p-value
PCI-H&N group	42(76.4)	11(14.1)	2(2.6)	55(100)	0.472	32(58.2)	22(40.0)	1(1.8)	55(100)	0.789
Control group	20(87.0)	3(13.0)	0	23(100)		13(56.5)	10(43.5)	0	23(100)	

Statistical test: Pearson Chi-square

Table 4.12: Patients' perceive on HRQoL for the past 7 days and from the last follow-up date at 1 month (n=78).

	HRQoL for the past 7 days					HRQoL from the last dental visits				
	Very good/ Good (n; %)	Average (n; %)	Poor/ Very poor (n; %)	Total (n; %)	p-value	Much improved/ A little improved (n; %)	The same (n; %)	A little worse/ Much worse (n; %)	Total (n; %)	p-value
PCI-H&N group	46(83.6)	9(16.4)	0	55(100)	0.114	43(78.2)	12(21.8)	0	55(100)	0.238
Control group	16(69.6)	7(30.4)	0	23(100)		15(65.2)	8(34.8)	0	23(100)	

Statistical test: Pearson Chi-square

Table 4.11 and Table 4.12 show no significant differences were observed between the two study groups for perceived overall HRQoL status for the past seven days and from the last dental visit. However, higher proportion among PCI-H&N study group at one month after follow-up consultation compared to the control group.

Table 4.13 shows patients‘ psychological distress levels at baseline and at post-consultation. At both period of time, results did not show any significant difference. However, the results showed a slightly higher proportion of lower distress level among the PCI-H&N study group at post-consultation (89.1%) compared to baseline (78.2%). A lower proportion was observed to have higher psychological distress level among the PCI –H&N study group (10.9%).

Table 4.13: Patients' perception on psychological distress level among post-treatment oral cancer patients for the past seven days (n=78).

Pre-consultation (Baseline)	Psychological distress level				Post-consultation (1 month)	Psychological distress level			
	<4	≥4	Total	p-value		<4	≥4	Total	p-value
PCI-H&N (n=55) %	43(78.2)	12(21.8)	55(100)	0.532	PCI-H&N (n=55) %	49(89.1)	6(10.9)	55(100)	1.00
Control (n=23) %	20(87.0)	3(13.0)	23(100)		Control (n=23) %	20(87.0)	3(13.0)	23(100)	

Statistical test: Fisher's exact test.

Further analysis was conducted for comparing outcomes of HRQoL, DT level and patients‘ satisfaction in terms of between and within study groups. Analysis were among samples who had completed data at baseline and at 1-month.

Table 4.14 shows the results of median difference of HRQoL domains after consultation session within the patients in the same study group of either PCI-H&N or the control group. These results were performed by a non-parametric test of Wilcoxon test and a confirmatory analysis by using the Paired-samples T-test.

Within the PCI-H&N group, the results showed a statistically significant difference for social well-being, emotional well-being, functional well-being, head and neck subscale, Malaysian-added questions, and total HRQoL score (FACT-H&N-MAQ) with time (one month after). MAQ among the PCI group showed a significant change after 1 month with improvement in the total MAQ score.

As for the control group, similar significant mean difference for social well-being relationship, functional well-being, head and neck subscale, Malaysian-added question and the total HRQoL score were observed. The median showed a decline value at 1 month compared at the baseline value.

Table 4.14: Median difference of HRQoL among post-treatment oral cancer patients within study groups after 1 month (n= 78)

Variables	PCI-H&N group (n=55)					Control group (n=23)				
	Baseline (median, IQR)	1 month (median, IQR)	Median difference within groups	p-value^1	p-value^2	Baseline (median, IQR)	1 month (median, IQR)	Means difference within groups	p-value^1	p-value^2
PWB	27.0 (24.0-28.0)	26.0 (21.0-28.0)	0.00 (3.0, 0.0)	0.244	-	28.0 (24.0-28.0)	25.0 (21.0-27.0)	0.50 (-6.5, 0.0)	0.077	-
SWB	22.0 (19.0-24.0)	19.0 (17.0-23.0)	-1.00 (-5.0,0.0)	0.001 *	0.001 *	24.0 (18.0-24.0)	18.0 (15.0-22.0)	-1.50 (-6.0,0.0)	0.026 *	0.020 *
EWB	22.0 (20.0-23.0)	20.0 (17.0-22.0)	-1.50 (-5.0, 0.0)	0.000 *	0.000 *	22.0 (20.0-24.0)	20.0 (14.8-23.0)	-1.50 (-6.0, 0.0)	0.039 *	0.517
FWB	27.0 (21.0-28.0)	21.0 (18.0-25.0)	-2.5 (-7.0, 0.0)	0.002 *	0.003 *	26.0 (23.0-28.0)	21.0 (16.0-23.0)	-6.0 (-9.5, -1.5)	0.001 *	0.000 *
HNC	26.0 (22.0-31.0)	26.0 (17.0-29.0)	-2.00 (-6.0, 3.0)	0.029 *	0.015 *	25.0 (21.0-29.0)	22.0 (15.0-25.0)	-4.50 (-10.5, -1.5)	0.002 *	0.003 *
MAQ	25.0 (21.0-27.0)	28.0 (24.0-30.0)	4.00 (0.0, 6.0)	0.000 *	0.000 *	25.0 (21.0-27.0)	26.0 (22.0-28.5)	2.50 (-1.0, 4.0)	0.063	-
FACT-HN-MAQ	147.0 (128.0-156.0)	135.5 (112.8-148.3)	-7.00 (-21.0, 11.0)	0.025 *	0.022 *	144.0 (125.0-157.0)	126.5 (119.5-134.5)	-12.50 (-28.0, -3.0)	0.003 *	0.001 *

Statistical test: Wilcoxon test; *$p<0.05^1$; Confirmatory analysis: Paired Samples T-test; *$p<0.05^2$

Table 4.15: Median difference of HRQoL among post-treatment oral cancer patients between study groups after 1 month (n= 78)

Variables	PCI-H&N group (n=55) Median(IQR)	Control group (n=23) Median(IQR)	Median difference between groups	p-value
PWB	26.0 (21.0-28.0)	25.0 (21.0-27.0)	1.0 (21.0-27.5)	0.290
SWB	19.0 (17.0-23.0)	18.0 (15.0-22.0)	1.0 (16.0-22.0)	0.651
EWB	20.0 (17.0-22.0)	20.0 (14.8-23.0)	0 (16.5-22.5)	0.586
FWB	21.0 (18.0-25.0)	21.0 (16.0-23.0)	0 (17-23.5)	0.563
HNC	26.0 (17.0-29.0)	22.0 (15.0-25.0)	4.0 (16.5-27.0)	0.104
MAQ	28.0 (24.0-30.0)	26.0 (22.0-28.5)	2.0 (23.0- 29.0)	0.158
FACT-HN-MAQ	135.5 (112.8-148.3)	126.5 (119.5-134.5)	9.0 (116.5- 144.0)	0.298

Statistical test: Mann-Whitney test

The median difference between study groups of PCI-H&N and Control group as shown at Table 4.15. As observed, no significant different in all the variables and there were no changes for emotional status and personal functions. However, there was a slight non-significant higher median among the PCI-H&N group compared to the control group.

Table 4.16 shows no significant difference in psychological distress levels within study groups among the post-treatment oral cancer patients for the past seven days. Both DT study groups showed an increase in the proportion at one month time compared at baseline. Similarly, no significant differences observed between the two study groups at 1 month time-point (Table 4.17).

Table 4.16: Differences of Psychological distress level among post-treatment oral cancer patients for the past seven days within study groups (n= 78)

PCI-H&N group (n=55)	Psychological distress level			Control group (n=23)	Psychological distress level		
	<4	≥4	p-value		<4	≥4	p-value
Baseline	43 (78.2)	12 (21.8)	0.180	Baseline	20 (87.0)	3 (13.0)	1.00
1 month	49 (89.1)	6 (10.9)		1 month	20 (87.0)	3 (13.0)	
difference within groups	10.9	10.9		difference within groups	1.00	1.00	

Statistical test: McNemar test

Table 4.17: Psychological distress level among post-treatment oral cancer patients for the past seven days between **study groups after 1 month (n= 78)**

	Psychological distress level <4	Psychological distress level ≥4	p-value
PCI-H&N group	49(89.1%)	6(10.9%)	0.809
Control group	20(90.5%)	3(9.5%)	
% Difference between groups	1.4%	1.4%	

Statistical test: Pearson Chi-square

Table 4.18 shows only the significant changes identified regarding the problems raised at baseline and after one month post-treatment among the PCI-H&N study group. As shown ‗fatigue‘, ‗tingling at hands and feet‘, and ‗financial/ insurance‘ problems were noted as significant changes at one month with lesser number of patients reported of these problems after one month. ―Fatigue" was one of the significant problems raised by the patients that showed 42.9% (3/7) of decrement at 1-month time point.

Table 4.18: Change in psychological distress specific problems selected by patients for the past 7 days at baseline and 1 month time-point for PCI-H&N study groups (n=55).

DT specific problems identified by patients	PCI-H&N (n=55)		
	At baseline (n, %)	1-month time point (n, %)	p-value
Fatigue	7(12.7)	4(57.1)	0.035
Tingling at hands/feet	5(9.1)	4(80.0)	0.006
Insurance/financial	3(5.5)	2(66.67)	0.006

Statistical analysis: McNemar test
*Table shows only problems at significant $p<0.05$

4.6 Patient satisfaction with follow-up consultation

Table 4.19 shows the descriptive findings on patients‘ satisfaction with the follow-up consultation session. No significant differences were observed between the three study groups. Generally, all post-treatment oral cancer patients were satisfied with the follow-up consultation for both groups.

Table 4.19: Patient’ satisfaction with the follow-up consultation (n=123)

	Variables	PCI-H&N (n= 85, 69.1%)	Control (n=38, 30.9%)	p-value
S1	The doctor gave me the opportunity to express my thoughts and concerns			
	satisfied	82 (96.5)	35 (92.1)	0.169
	neither	1(1.2)	3(7.9)	
	dissatisfied	2 (2.4)	0	
S2	I feel the doctor understood me.			
	satisfied	85 (100)	37 (97.4)	0.324
	neither	0	1 (2.6)	
	dissatisfied	0	0	
S3	My doctor explained things in a way that was easy for me to understand.			
	satisfied	84(98.8)	36 (94.8)	0.554
	neither	1 (1.2)	1 (2.6)	
	dissatisfied	0	1 (2.6)	
S4	The doctor involved me in the decision-making.			
	satisfied	82 (96.5)	36 (94.8)	0.678
	neither	3 (3.5)	1 (2.6)	
	dissatisfied	0	1 (2.6)	
S5	My doctor spent enough time with me during consultation session.			
	satisfied	83 (97.6)	37 (97.4)	0.315
	neither	0	1 (2.6)	
	dissatisfied	2 (2.4)	0	

Statistical test: Pearson chi-square test

Table 4.19: Patient' satisfaction with the follow-up consultation session (n=123). (continued)

	Variables	PCI-H&N (n= 85, 69.1%)	Control (n=38, 30.9%)	p-value
S6	My doctor informed about services of other health and social care providers that I may require.			
	satisfied	78 (91.8)	34 (89.5)	0.857
	neither	7 (8.2)	4 (10.5)	
	dissatisfied	0	0	
S7	I am satisfied with my doctor's responses to all my expectations and concerns.			
	satisfied	81 (95.3)	37 (97.4)	0.857
	neither	3 (3.5)	1 (2.6)	
	dissatisfied	1 (1.2)	0	

Statistical test: Pearson chi-square test

4.7 Association of PCI-H&N among post-treatment oral cancer patients

4.7.1 Patient sociodemographic background

Table 4.20 shows the possible association of patients' sociodemographic background with number of patients' concerns by total group score of low and high number of patients' concerns selected. There was no significant association between number of concerns and patients sociodemographic background. Nevertheless, this study group had higher proportion of females (61.2%) compared to males (38.8%) with both groups showed higher proportion at the lower number (0-3) of concerns selected.

Mean age for both groups were almost similar at 58.9 ± 12.8 years old. It was observed that patients among 51 – 65 years old had less number of concerns (0-3) selected for follow-up consultation compared to other age of study groups.

Majority of patients are married with highest proportion in lower number (0-3) of concerns selected. More than 50% of Chinese patients (69.6%) raised less number of concerns (0-3). Equal proportion was observed among the tertiary education patients.

Table 4.20: Number of patients' concerns by their sociodemographic background (n= 85).

Variables		PCI-H&N concerns selected			
		Total n,%	Low number of concerns (0-3) (n=48),%	High number of concerns (4-17) (n=37),%	p-value
Gender	Male	33(38.8)	19(57.6)	14(42.4)	0.870
	Female	52(61.2)	29(55.8)	23(44.2)	
Age	Mean (SD) :	58.9 ± 12.8	59.35± 10.78	58.30± 15.13	*0.708
	18- 50	23(27.1)	11(47.8)	12(52.2)	0.310
	51-65	36(42.4)	24(66.7)	12(56.7)	
	66-100	26(30.6)	13(50.0)	13(50.0)	
Marital status	Married	58 (68.2)	32 (55.2)	26 (44.8)	0.936
	Single	12 (14.1)	7 (58.3)	5 (41.7)	
	Divorce / widow	15(17.6)	9 (60.0)	6 (40.0)	
Ethnicity	Malay	36 (42.4)	17 (47.2)	19 (52.7)	0.411
	Chinese	23 (27.1)	16 (69.6)	7 (30.4)	
	Indian	7 (8.2)	4 (57.1)	3 (42.9)	
	Bumiputera /Others	19 (22.4)	11 (57.9)	8(42.1)	
Religion	Muslim	38 (44.7)	19 (50.0)	19 (50.0)	0.621
	Christian	22 (25.9)	13(59.1)	9 (40.9)	
	Buddhist	15 (17.6)	10 (66.7)	5 (33.3)	
	Hindu	7 (8.2)	5 (71.4)	2(28.6)	
	Others	3 (3.5)	1 (33.3)	2 (66.7)	
Education level	Tertiary	44 (51.8)	22 (50.0)	22 (50.0)	0.421
	Secondary	29 (34.1)	19 (65.5)	10 (34.5)	
	No formal education	12 (14.1)	7 (58.3)	5 (41.7)	

Statistical test: Pearson chi-square; *Independent sample t-test

4.7.2 Patient cancer characteristic

Table 4.21 shows the association of patient cancer characteristic with the number of concerns selected (low number of concerns: 0-3 items, high number of concerns: 4-17 items. The number of patient concerns was not significantly associated with the patients‘ profile except for the ‗time after treatment completed‘ (p<0.001**).** Although it was not significant, almost all the cancer sites were shown to select less number of patients‘ concerns except cancer sites at maxillary and gingivae, and in terms of oral cancer staging, higher proportion was also observed among the low number of concerns selected for all cancer staging groups.

This study suggested that a high number of concerns was associated with the earlier phase of post-treatment because a significant 84.2% among the one-month until one-year post-treatment patients had a high number of concerns selected whereas fewer issues of concerns (0-3 concerns) were selected by 75% of those who had completed treatment three to five years ago. Further analysis was conducted to determine which group showed the significant difference. From the adjusted residual value, groups that showed significant difference were among the ‗>1 month until 1 year‘ with high number of concerns selected, and the ‗more than 1 year till 3 years‘ and the ‗more than 3 till 5 years‘ groups with low number of concerns selected. Subsequent analysis showed some significant PCI-H&N items associated with the time after treatment completed (Table 4.22).

Table 4.21: Number of patients' concerns by their cancer characteristic (n= 85).

Variables		PCI-H&N concerns selected				
		Total	Low number of concerns (0-3) (n=48)	High number of concerns (4-17) (n= 37)	X^2	p-value
Cancer site	Tongue	49(57.6)	26(53.1)	23(46.9)	0.547	0.460
	Buccal	12(14.1)	8(66.7)	4(33.3)	0.591	0.442
	Mandible	8(9.4)	5(62.5)	3(37.5)	0.003	0.953
	Lips	7(8.2)	5(71.4)	2(28.6)	0.694	0.405
	Alveolus	4(4.7)	2(50.0)	2(50.0)	0.071	0.789
	Maxillary	2(2.4)	1(50.0)	1(50.0)	0.035	0.852
	Palate	2(2.4)	2(100)	0	1.579	0.209
	Gingivae	1(1.2)	0	1(100)	1.313	0.252
	Salivary gland	-	-	-	-	-
	Floor of the mouth	-	-	-	-	-
TNM staging	I	32 (37.6)	18 (56.3)	14 (43.7)	1.150	0.771
	II	25 (29.4)	13 (52.0)	12 (48.0)		
	III	13 (15.3)	9 (69.2)	4 (30.8)		
	IV	15 (17.6)	8 (53.3)	7 (46.7)		
Cancer treatment done	Surgery	45 (52.9)	24(53.3)	21(46.7)	0.383	0.536
	Radiotherapy/ chemotherapy	39 (45.9)	23(59.0)	16(41.0)	0.184	0.688
	Surgery & radiotherapy/chemotherapy	1(1.2)	1(100)	0	0.780	0.377
time after treatment completed (n=67)	1 month till 1 year	19 (28.4)	3 (15.8)	16 (84.2)^	16.087	0.001*
	>1 year till 3 years	28 (41.8)	20 (71.4)^	8 (28.6)		
	>3years till 5 years	8 (11.9)	6 (75.0)^	2 (25.0)		
	>5 years	12 (17.9)	7 (58.3)	5 (41.7)		

Statistical test: Pearson Chi-square, p<0.001*; Z-score > 1.96^

Further analysis showed the significant of PCI-H&N items that were associated with the _time after treatment completed‘ (Table 4.22). The significant items were _chewing/ eating‘, _mouth opening‘, _swelling‘, _weight‘, _ability to perform daily routine‘, _concerns on cancer treatment‘ and _health supplement/ diet‘. The analysis also suggested that the significant PCI-H&N specific concerns were highly significant among patients in the category of _one month until less than one year‘ after completing treatment (Fisher‘s Exact test, z-score> 1.96^).

Table 4.22: Association between time after treatment completion and PCI- H&N items selected (n=85).

‗Time after treatment completed‘	Physical status domain (p<0.001)				Personal function domain (p<0.05)	Treatment related domain (p<0.001)	
	Chewing/ Eating (n;%)	Mouth opening (n;%)	Swelling (n;%)	Weight (n;%)	Ability to performe (n;%)	Cancer treatment (n;%)	Supplement/ diet related (n;%)
1 month till 1 year	10(11.8)^	6(7.1)^	5(5.9)^	4(4.7)^	5(5.9)^	7(8.2)^	4(4.7)^
>1 year till 3 years	3 (3.5)	0	0	0	0	2(2.4)	0
>3years till 5 years	0	1(1.2)	0	1(1.2)	0	0	0
>5 years	2(2.4)	0	1(1.2)	0	0	0	0
p-value	0.003	0.002	0.013	0.021	0.005	0.015	0.015

Statistical analysis: Fisher‘s Exact test, z-score> 1.96^

*The table shows only items with significant association p<0.05

4.7.3 Patient Health-related Quality of Life

a) Number of PCI-HN selected based on patients' HRQoL

A significant (p-value= 0.003) higher proportion of numbers of concerns was associated among patients with lower HRQoL (Table 4.23). Better HRQoL revealed lesser patient concerns as observed by the adjusted residual value (z-score). Approximately 70% of post-treatment oral cancer patients with lower HRQoL scores (77-140) had significantly more numbers of concerns (4-17 items) and vice versa (p-value= 0.003, Spearman correlation r=0.466). This study found that patients raised more concerns when they had low HRQoL scores. Figure 4.5 shows that high numbers of patients' concerns with median (IQR) of 5 (3-7) (n=23) were reported among those with median (IQR) HRQoL of 113 (91-125).

Table 4.23: The association of patients' concerns by number of concerns selected with HRQoL (n= 85)

PCI-H&N concern selected	HRQoL Low score (77-140)	 High score (141- 167)	Total	P-value
Low number of concerns (0-3)	18(37.5)	30(62.5)^	48(100)	0.003*
High number of concerns (4-17)	26(70.3)^	11(29.7)	37 (100)	

Statistical test: Pearson chi-square; p-value<0.05; z-score > 1.96^

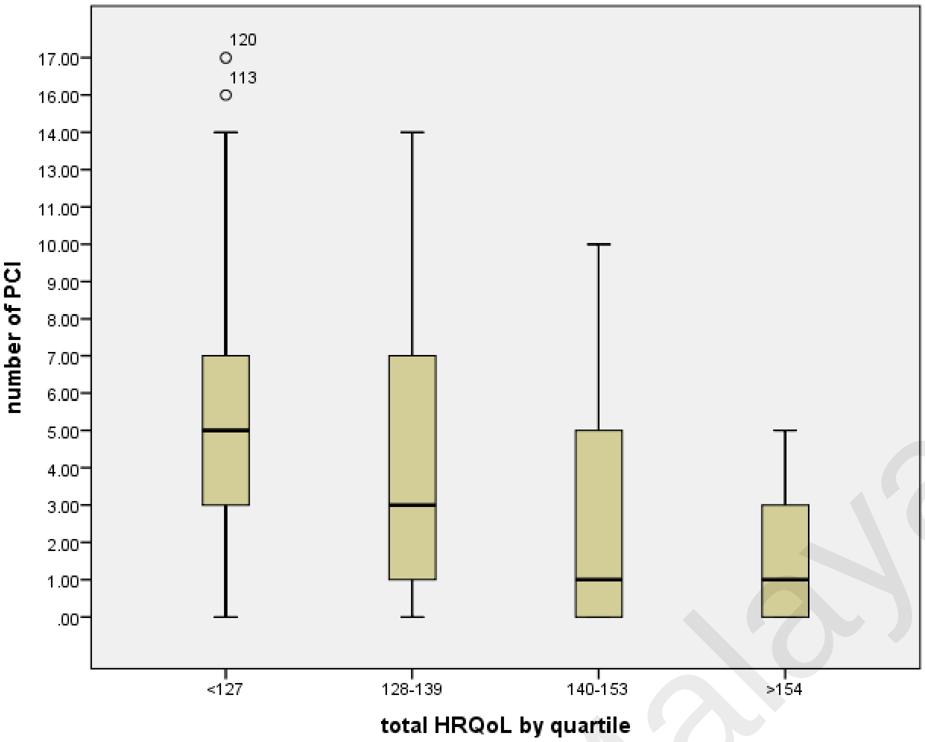


Figure 4.5: Boxplot of numbers of patients' concern by HRQoL quartile (n= 85)

b) Correlation and regression analysis between HRQoL and PCI-H&N domains.

The assumptions of normality, linearity and homoscedasticity were found not to be supported. Table 4.24 shows the correlation analysis revealed that patients‘ HRQoL was significantly correlated with patients‘ physical status (p<0.0001), personal function (p<0.0001), treatment related (p=0.034), social care and social well-being (p=0.040), and emotional (p=0.002) domains.

Table 4.24: Correlation between patient HRQoL and PCI-H&N domains (n=85).

HRQoL	PCI-H&N domains						
	Physical Status	Personal Function	Cancer treatment related	Social care& social well-being	Economic status	Emotional status	Spiritual well-being
Correlation Coefficient	-0.415	-0.460	-0.231	-0.223	-.016	-0.329	-0.0224
p-value	**0.0001***	**0.0001***	**0.034***	**0.040***	0.885	**0.002***	0.824

Statistical test: Spearman correlation, p< 0.05*

Further Multiple Linear Regression revealed a significant 38% variance in HRQoL score was explained by patients‘ personal status and physical functions domains (multiple linear regression: $p< 0.0001$; $R^2= 0.393$, adjusted $R^2= 0.338$, F (7, 77) = 7.133) as shown at Table 4.25. Among the PCI-H&N domains, only personal functions and physical functions were significantly difference. Personal functions strongly predicted patients‘ lower HRQoL (standardised coefficients= -0.601, p<0.0001).

c) Correlation and regression analysis between patient HRQoL and PCI-H&N items.

The assumptions of normality, linearity and homoscedasticity were assessed. From test of normality, a significant Kolmogorov-Smirnov statistic (sig<0.001) was observed, and indicates that the data are not normally distributed. The normal Q-Q plot showed a normal distribution however the scatterplot for HRQoL and the PCI-H&N items showed no linear relationship therefore a Spearman‘s Rho product-moment was used. Significant PCI-H&N items from the Spearman correlation (Table 4.26) were further entered for Multiple Linear Regression (MLR).

Table 4.25: Multiple Linear regression analysis of PCI-H&N domains associated with patient HRQoL (n= 85).

Items	B	95% CI	β	*sr*^{2}	*p*-value
Constant	145.028				
Physical status	-2.577	-4.858, -0.295	-0.273	-0.200	**0.027***
Personal function	-18.669	-26.541, -10.797	-0.601	-0.419	**0.000****
Cancer treatment related	4.557	-1.449, 10.562	0.166	0.134	0.135
Social care& social well-being	5.146	-6.440, 16.733	0.091	0.079	0.379
Economic status	8.972	-6.962, 24.906	0.108	0.100	0.266
Emotional status	1.273	-3.894, 6.441	0.056	0.044	0.625
Spiritual well-being	9.964	-25.413, 45.342	0.051	0.050	0.577

Statistical analysis: Multiple Linear Regression, p<0.05*, p<0.0001**

Table 4.26: Correlation between patient HRQoL and PCI-H&N items (n=85).

	PCI-H&N items				
HRQoL	Chewing/ Eating	Speech	Mouth	Dry mouth	Swallowing
Correlation Coefficient	-0.558	-0.232	-0.271	-0.295	-.280
p-value	0.0001**	0.033*	0.012*	0.006*	0.009*

Statistical analysis: Spearman correlation, p<0.05*, p<0.0001**

Table 4.26: Correlation between total patient HRQoL and PCI-H&N items (n=85) (continued).

	PCI-H&N items				
HRQoL	Appearance	Recreation	Recur	Taste	Sleep
Correlation Coefficient	-0.305	-0.340	-0.288	-0.304	-0.224
p-value	0.005*	0.001*	0.008*	0.005*	0.039*

Statistical analysis: Spearman correlation, $p<0.05$*, $p<0.0001$*

Assumptions were assessed prior interpreting MLR of HRQoL and PCI-H&N items. The assumptions of normality, linearity and homoscedasticity of residuals were not met. From the residual statistic table, the maximum Mahalanobis distance of 46.4 exceed the critical X^2 for df= 10 of 29.6 which need to be concerned on multivariate outliers. Based on the coefficient table, high tolerances for all the predictors (>0.1) in the regression model indicated that multicollinearity would not interfere with the ability to interpret the outcome of the multiple regression analysis.

The model summary showed a significant 54.2% variance in patients‘ total HRQoL score was explained by the predictors ($p< 0.0001$; $R^2= 0.542$, adjusted $R^2= 0.480$, F(10,74)= 8.77). This analysis suggested that patients‘ HRQoL can be moderately predicted by ‗appearance‘ and ‗ability to perform recreation activities‘, with ‗chewing and eating‘ as a stronger predictor for low HRQoL score (standardised coefficients= -0.395, $p<0.0001$), as shown in Table 4.27.

Table 4.27: Multiple Linear regression analysis of PCI items for patients' HRQoL

Items	B	95% CI	β	sr^2	*p*-value
Constant	147.42				
Physical status					
Chewing/ Eating	-20.54	-31.00, -10.07	-0.395	0.095	0.000
Personal function					
Appearance	-28.93	-45.99, -11.88	-0.289	0.071	0.030
Recreation	-16.80	-31.09, -2.50	-0.218	0.034	0.022

*Table shows only items with significant association (p< 0.05).

i) Patients psychological distress

a) Numbers of PCI-HN selected based on patient psychological distress level.

At a cut-off point of four concerns, psychological distress level was not significantly associated with the number of patients‘ concerns (p-value> 0.05). This study demonstrated a higher proportion of patients with low-risk psychological distress levels regardless of the number of concerns selected (Table 4.28).

Table 4.28: The association of patients' concerns by number of concerns selected with patient psychological distress (n= 85).

PCI-H&N concern selected	Psychological distress level		Total	P-value
	<4	≥4		
Low number of concerns (0-3)	40(83.3)	8(16.7)	48(100)	0.246
High number of concerns (4-17)	27(73.0)	10(27.0)	37 (100)	

Statistical test: Pearson chi-square

b) Correlation and regression analysis between patient psychological distress level and PCI-H&N domains.

A Pearson chi-square was conducted to assess the linear association between psychological distress level and PCI-H&N domains. Based on the univariate analysis, significant PCI-H&N domains as shown at Table 4.29. Patients‘ DT level was significantly correlated with patients‘ emotional status (p=0.009), and social care and social well-being (p=0.034). All items of p<0.05 were further analysed in the Multivariate Logistic Regression (MLR) in order to estimate the probability of psychological distress level among the post-treatment oral cancer patients based on assumption of PCI-H&N domains selected.

Table 4.29: Univariate analysis between psychological distress and PCI-H&N domains (n=85).

PCI-H&N domains	Psychological distress level <4 (n,%)	 ≥ 4 (n,%)	P-value
Physical Status	46(54.1)	13(15.3)	0.750
Personal Function	14(16.5)	8(9.4)	0.089
Cancer treatment related	17(20)	6(7.1)	0.616
Social care& social well-being	3(3.5)	4(4.7)	**0.034***
Economic status	4(4.7)	2(2.4)	0.579
Emotional status	23(27.1)	13(15.3)	**0.009***
Spiritual well-being	0	1(1.2)	0.106

Statistical analysis: Chi-square, p<0.05*

The omnibus model for logistic regression analysis was statistically significant, X^2=15.6 (p<0.05), Cox and Snell R^2= 0.119, Nagelkerke R^2= 0.190. The model was

83.7% accurate in its predictions of possible distress by PCI-H&N domains. Hosmer and Lemeshow test results showed the model involving PCI-H&N items fit in predicting distress level among post-treatment oral cancer patients (X^2=1.262, p=0.974). Coefficients for the model as shown at Table 4.30.

Table 4.30: Multivariate Logistic Regression analysis of PCI domain associated with psychological distress level (n= 85).

PCI-H&N items	Crude OR	Adjusted OR	95% CI	p-value
Constant	-1.67	0.19		
Emotional status	-1.44	0.24	0.060, 0.936	0.040*

Statistical test: Multivariate Logistic Regression; p<0.05*
*Table shows only items with significant association (p< 0.05).

As demonstrated in Table 4.30, emotional status was the only predictor in PCI-H&N domain for DT level among post-treatment oral cancer patients. MLR analysis revealed that the probability of patients with a higher tendency of psychological distress (DT >4) was 24% more if they had emotional concerns. Other PCI-H&N domains did not revealed to be significant.

c) Correlation and regression analysis between patient psychological distress level and PCI-H&N items.

A Pearson chi-square was conducted to assess the linear association between psychological distress and PCI-H&N items. Table 4.31 shows the significant PCI-H&N items (p<0.05). All items of p<0.05 were further analysed in the Multivariate Logistic Regression (MLR).

Table 4.31: Univariate analysis between psychological distress level and PCI-H&N items (n=85).

DT level	Tiredness (n.%)	Pain other than H&N (n,%)	Sleep (n,%)	Recreation (n,%)	Support (n,%)	Angry (n,%)	Anxiety (n,%)	Coping (n,%)	Depress (n,%)
<4	2(2.4)	1(1.2)	4(4.7)	3(3.5)	1(1.2)	0	2(2.4)	1(1.2)	1(1.2)
≥4	3(3.5)	2(2.4)	5(5.9)	4(4.7)	2(2.4)	3(3.5)	3(3.5)	2(2.4)	3(3.5)
p-value	0.029*	0.050	0.008*	0.015*	0.050	0.001*	0.029*	0.050	0.007*

Statistical analysis: Chi-square, p<0.05*
*Table shows only items with significant association (p< 0.05).

A Multivariate Logistic Regression was used to estimate the probability of DT level among the post-treatment oral cancer patients based on assumption of PCI-H&N items selected.

Assumptions testing were conducted prior the analysis. Multicollinearity checks was conducted assessing correlations between predictors and it was suggested that multicollinearity is possible to be an issue as some of the correlations between predictors is significant (p<0.05) and however the Pearson‘s r < 0.80.

In the classification table for Block 0, the model is able to predict DT level by 78.8 % of the PCI-H&N items. Whereas in the Classification Table for Block 1, the model is able to estimate DT level by 84.7 % of the items selected.

The omnibus model for logistic regression analysis was statistically significant, X^2=21.1 (p=0.004), Cox and Snell R^2= 0.220, Nagelkerke R^2= 0.341. Based on the classification table, the model was 84.7% accurate in its predictions of possible distress. Hosmer and Lemeshow test results showed the model involving PCI-H&N items fit in predicting distress level among post-treatment oral cancer patients (X^2=0.022, p=0.884). Variables in the equation table showed only ‗ability to perform recreation activities‘ and ‗feeling depressed/ sad‘ significantly improves the predictive ability of the model (p<0.05) and 95% C1 does not encompass 1.0. Coefficients for the model as shown in Table 4.32.

Table 4.32: Multivariate Logistic Regression analysis of PCI items associated with psychological distress level (n= 123).

PCI-H&N items	Crude OR	Adjusted OR	95% CI	p-value
Constant	-2.21	0.11		
Ability to perform recreation activities	1.95	7.03	1.161, 42.606	0.034
Feeling depress	2.66	14.34	1.152, 178.51	0.038

Statistical test: Multivariate Logistic Regression.
*Table shows only items with significant association (p< 0.05).

As demonstrated in Table 4.32, ‗ability to perform recreational activities‘ and ‗depress‘ were significant predictor for psychological distress among post-treatment oral cancer patients. The MLR analysis revealed that if the patients select ‗ability to perform recreation activities‘ and ‗feeling depress‘, they were 7.03 and 14.34 times respectively are more likely to develop psychological distress compared if the patients selected other PCI-H&N items.

ii) Patient satisfaction with the follow-up consultation.

a) Number of PCI-HN selected based on patient satisfaction with follow-up consultation.

Table 4.33 shows the non-significant association between number of concerns selected by the patients and their‘ satisfaction with the follow-up consultation. This analysis showed that patients who were satisfied with the consultation had selected less concerns (0-3 items).

Table 4.33: The association of number of patients' concerns selected with patients'

satisfaction with follow-up consultation (n= 85).

	Patient satisfaction with follow-up consultation				
Number of PCI-H&N selected	Very Satisfied/ satisfied (n; %)	Neither (n; %)	Dissatisfied / Very Dissatisfied (n; %)	Total	*p*-value
Low number of concerns (0-3)	45 (52.9)	3 (3.5)	0	79 (92.9)	0.740
High number of concerns (4-17)	34 (40)	3 (3.5)	0	6 (7.1)	

Statistical test: Pearson chi-square

b) Association between patients‘ satisfaction with the follow-up consultation and PCI-H&N domains.

A Pearson chi-square was conducted to assess the linear association between post-treatment oral cancer patients‘ satisfaction with follow-up consultation and PCI-H&N domains (Table 4.34). Based on the univariate analysis, no significant difference was observed between the two variables. Therefore, no further analysis was performed.

Table 4.34: Univariate analysis between patient satisfaction with follow-up consultation and PCI-H&N domains (n=85).

	Patient satisfaction with follow-up consultation			
PCI-H&N domains	Very Satisfied/ satisfied (n; %)	Neither (n; %)	Dissatisfied / Very Dissatisfied (n; %)	*p*-value
Physical Status	54(63.5)	5(9.3)	0	0.742
Personal Function	22(25.9)	0	0	0.332
Cancer treatment related	20(23.5)	3(3.5)	0	0.429
Social care& social well-being	7(8.2)	0	0	0.745
Economic status	6(7.1)	0	0	0.778
Emotional status	35(41.2)	1(1.2)	0	0.424
Spiritual well-being	1(1.2)	0	0	0.951

Statistical analysis: Chi-square, p<0.05

4.8 Usefulness and feasibility of PCI-H&N during the follow-up consultation

4.8.1 Usefulness and feasibility feedback from the patients

Patients‘ feedback on PCI-H&N is as shown at Table 4.35. From the Pearson chi-square test, there was no significant differences identified between the two versions. Patients agreed that the prompt list did not consume a lot of time to be completed, able to identify their concerns, and would like to use the prompt list in the future (84.7%).

Table 4.35: Patients' feedback on PCI-H&N used (n=85)

Variables	PCI-H&N Paper (n=55) n(%)	PCI-H&N Computerised web-based (n=30) n(%)	p-value
SF1. Did filling the prompt list take a lot of your time?			
Yes	8 (14.5)	2(0.07)	0.11
SF 2. Helps to identify your concerns and needs more effectively			
Yes	50(90.9)	27(90.0)	0.12
SF 3. Helps to remember the issues that you wanted to discussed with your clinician?			
Yes	47(85.5)	27(90.0)	0.05
SF 4. Would you like to use the prompt list for future visits?			
Yes	45(81.8)	21(70.0)	0.13

Table 4.35: Patients‘ feedback on PCI-H&N used (n= 85) (continued)

Variables		PCI-H&N		p-value
		Paper (n=55) n(%)	Computerised web-based (n=30) n(%)	
SF 5. Are you comfortable of using the paper/ touch screen version?				
	Very easy/ easy	42 (76.4)	17(56.7)	0.19
	Moderately easy	4(7.3)	5(16.6)	
	Difficult/ very difficult	9(16,4)	8(26.7)	
SF 6. How confident did you feel completing the PCI on a paper/ touch screen version without help?				
(n=69) NA : 16	Very confident/ somewhat confident	38(82.6)	14(60.9)	0.17
	Neither	3(6.5)	4(17.4)	
	Little confident/ not at all confident	5(10.9)	5(21.7)	

Statistical test: Fisher exact test, NA: not available

4.8.2 Usefulness and feasibility feedback from the clinicians and assistants

The feedback on PCI-H&N used was also obtained from the clinicians and the assistants who involved directly with this study. Table 4.36 is the descriptive feedback form the clinicians (n=11). All of the clinicians agreed that the PCI-H&N helped in a focused consultation targeting at patients‘ concerns (100%) and the prompt list helped their patients to identify issues that they want to discuss with their clinicians (100%). However, 72.7% of the clinicians think that the prompt list prolonged the consultation session.

In term of its usefulness, the prompt list helps as a quick glimpse on patients‘ concerns (score mod: 9) and addressing patients‘ concerns (score mod: 8). As for practicality of its use in the clinical setting, majority agreed the prompt list was practical to be use during the follow-up consultation (score mod: 7) and 81.8% of the clinicians were in support on PCI-H&N usage in future. More than 70% of them prefer the paper version compare to the computerised web-based version.

Table 4.36: Clinician’s feedback on PCI-H&N used (n= 11)

	Variables	Number
G1	Did you refer to the prompt list before conducting the consultation?	
	Yes	11 (100%)
G2	Do you feel that the prompt list t helped you to be more focused in addressing patient concerns during consultation?	
	Yes	11(100%)
G3	Did it help prompt your patients to recall the issues that he/she had selected to discuss with you during consultation?	
	Yes	11(100%)
G4	Do you think that referring to the prompt list increases the length of consultation time?	
	Yes	8(72.7%)
G5-a	Its usefulness to you as a quick glimpse/ snapshot of patient‘s concerns.	
	Score Range : 7-9	
	Score Mod: 9	
G5-b	Practicality in using it for all new and follow-up patients visits in your clinical setting.	
	Score Range : 5-9	
	Score Mod: 7	
G5-c	The ability of it to adequately address patient‘s concerns during your consultation.	
	Score Range : 7-10	
	Score Mod: 8	
G6	Would you be agreeable to use the prompt list in the future during follow-up consultation in your clinical setting?	
	Yes	9(81.8%)
G7	If you can choose, which PCI version would you prefer most?	
	Computerised web-based	3(27.3%)
	Paper	6(72.7%)

Table 4.37: Assistant's feedback on PCI-H&N used (n= 5)

	Variables	(n)
H1	Was it difficult for you to explain the purpose of the prompt list to the patients?	
	Yes	1(20%)
H2	When you introduce the prompt list to the patients, did it disrupt the registration process?	
	Yes	1(20%)
H3	Do you think the completion of the prompt list by patients prolong the registration time?	
	Yes	0
H4	Which are the most suitable time to fill up the prompt list ?	
	at registration counter on appointment day	4(80%)
	to fill up at home before commence the next follow-up clinic	1(20%)
H5	Which is your preference, paper or computerized web-based PCI-H&N?	
	paper version	3(60%)
	computerized web-based version	2(40%)

Table 4.37 shows the feedback from the assistants involved (n=5). Generally, the feedback were positive. The assistants did not find the PCI-H&N as a burden as 80 % of them that it was not difficult to explain to the patients and did not disrupt the registration process whereas, 100% agreed PCI-H&N did not prolong registration time.

As for preference, the assistants prefer the prompt list to be filled-up at the registration counter on their appointment day and 60% chose paper-version compared to computerised web-based.

4.9 Time taken by the patients to complete the prompt list

Time taken to complete both versions of PCI-H&N and the consultation duration among those using the PCI-H&N used is shown in Table 4.38. From the Mann-Whitney test, both versions of PCI-H&N showed strong significant (p< 0.0001) difference for the time taken to complete the prompt list. PCI-H&N in paper version took a shorter time to be completed by patients (4.0 ± 3.7 mins; 95% CI: 3.87, 5.87) compared to the computerised web-based version (6.0 ± 4.5 mins; 95% CI: 5.55, 8.92). There was no significant differences observed in term of follow-up consultation time.

Table 4.38: Time taken by post-treatment oral cancer patients to complete the PCI-H&N and duration of follow-up consultation among PCI-H&N user (n= 85).

User	PCI-H&N	Median (SD) time	95% CI	Range	p-value
Patients	Paper version (n= 55)	4.0 ± 3.7 mins	3.87,5.87 mins	2 -20 mins	0.0000*
	Computerised web-based (n=30)	6.0 ± 4.5 mins	5.55, 8.92 mins	1 – 22 mins	
Clinicians	Paper version (n= 32)	15.0 ± 16.6 mins	14.0,25.0 mins	1-60 mins	0.329
	Computerised web-based (n=27)	13± 21.5 mins	11, 29 mins	1-65 mins	

Statistical test: Mann-Whitney test, P<0.001*

4.10 Qualitative feedback of the focus group discussion (FGD) among health personnel.

Focus group discussions (FGD) were conducted at individual centres (QE, HUS, HAS and HSJ) by the researcher. The other two centres (OMFS, HKL and OMFS,UM were not included in the FGD as it was conducted by the researcher for the assistant‘s role due to shortage of manpower at the sites. Thus, the role of the assistant could not be obtained in FGD. The thematic analysis were guided based on the seven domains from FRAME-IT framework themes to answer the specific objectives. Please refer Appendix R. Data gathered from the themes were analysed and presented according to study objectives for a more meaningful study results. The information generated from the FGD sessions among the health care personnel were very valuable as it provide their experiences, limitations and positive input on improvement for future implementation.

4.10.1 Profiles of participants

Table 4.39 shows the participants involved in FGD sessions. A total of 16 participants took part in the session with majority were females (n=9, %). The duration of employment among the participants ranged from three to twenty years with median: 9 (6-11) years (Table 4.39). The FGD groups included Dental Specialists (n=7), Dental officers (n=5) and Dental Surgeon Assistants (n=4). The identification of participants as shown at Table 4.40.

Table 4.39: Summarised participant's profile (n=16)

Participant's profiles	Total	QEH	HUS	HSA	HSJ
Male	7	3	1	2	1
Female	9	2	4	2	1
Years of service among the clinicians					
1-4	3	2	-	-	1
5-10	6	2	2	1	1
>10	3	-	2	1	-
Median (IQR)			9 (6,11) years		
Range			3-24 years		
Designation					
Specialist	7	2	3	1	1
Dental Officer	5	2	1	1	1
Dental Assistant	4	1	1	2	-

QEH: Queen Elizabeth Hospital
HUS: Sarawak General Hospital
HAS: Sultanah Aminah Hospital
HSJ: Seberang Jaya Hospita

Table 4.40: Participants' identification profile

ID	Gender	Hospital	Designation
P1	Male	QEH	Specialist
P2	Male	QEH	Specialist
P3	Female	QEH	Dental Officer
P4	Female	QEH	Dental Officer
P5	Male	QEH	Dental Assistant
P6	Female	HUS	Specialist
P7	Female	HUS	Specialist
P8	Male	HUS	Specialist
P9	Female	HUS	Dental Officer
P10	Female	HUS	Dental Assistant
P11	Female	HSA	Specialist
P12	Male	HSA	Dental Officer
P13	Male	HSA	Dental Assistant
P14	Female	HSA	Dental Assistant
P15	Male	HSJ	Specialist
P16	Female	HSJ	Dental Officer

4.10.2 Experiences of oral health personnel in implementing the study.

a) PCI-H&N paper-version as the preferred version among health personnel

Majority of clinicians and dental assistants would prefer the paper version of PCI-H&N compared to the computerised web-based version due to the limitation of IT facilities especially when the hospital patient‘s management records were conducted manually by pen and paper.

The paper version was also seem to be more feasible and practical for patients‘ use when a portable electric devices such as androids or iPads were unavailable and a paper version was deemed to be more approachable among the elderly. Computerised web-based version was demonstrated as easy to be used among those with IT knowledge and among the educated patients.

"we still prefer paper and pen compared to web-based. I know web-based is the better feature, maybe when our hospital does have computer system and easily accessible web system, maybe yes. But, currently, we prefer pen and paper for this kind of the survey. It could be easier for us also because everything we do here is pen and paper. With this pen and paper, you can fill out the form easier and patient doesn"t have to go to the computer to fill out the form".

P12 (DO, HSA)

"I think if possible, we want paper-based."

P1 (Specialist, QEH)

"the paper based is easier, because it is also physical there, so you can just show the patient. Sometimes, with the screen, the patient like haa, the elderly like haa, no more, ok."

P3 (DO, QEH)

"Initially, we felt that the web-based is difficult. But, in actual fact, it is not. It is easy, it just patient. I think for educated patients, they can actually do by themselves. I found it is actually easy web-based. You just click, click, click"

P6 (Specialist,HUS)

b) PCI-H&N is a simple prompt list that can be conducted by DSA

The PCI-H&N used in this study was in two languages of English and Malay. PCI-H&N is a simple prompt list that can be easily performed by the DSA.

"Sebab kita ada English and Malay version. Mereka boleh conduct, no issue. Tak banyak yang teknikal sangat kan?"

Translated: Because we have the English and Malay versions, They can conduct, no issue. There aren't many technical ones

P1 (Specialist, QEH)

c) Patient's ability to complete PCI-H&N with and without assistance.

Some patients were able to complete the prompt list independently. On the other hand, some patients especially the elderly require assistance in completing the PCI-H&N in either version as they are not confident in completing it independently. Main post-treatment oral cancer patients in Malaysia are mainly the elderly.

…"understands quite well. So, he doesn"t need your help, he fills everything on his own." P10 (DSA, HUS)

…."most of the patients are elderly patients. So, I think they are not confident enough to answer the question by themselves. And then, if you look at the feasibility, I think if you ask anyone, they would rather to be assisted to read the questionnaire. Because sometimes, they don"t understand the question"

P1 (Specialist, QEH)

"bagi pada patient tapi kebanyakan mereka akan minta bantuan lah untuk isi. Dia tak faham"

Translated: "given to the patients, but mostly they will ask for help to fill. They don't understand"

P5 (DSA, QEH)

d) PCI-H&N as a standard guideline for clinicians during post-treatment follow-up consultation.

The clinicians‘ communication skills during the follow-up consultation varies depending on their experiences in managing oral cancer patients. Occasionally, due to time constraints, the clinicians noticed that this prompt list can prevent them bypassing issues of their patients‘ concerns. Moreover, it guides the patients to share their concerns for better management of their treatment and well-being. PCI-H&N also enable patients and clinicians to understand better the impact from oral cancer and its treatment. Thus, PCI-H&N was deemed to be practical tool during the follow-up consultation to standardise patient management.

.."depends on the skills of the clinician, different experience with it, different exposure, right? Although you maybe some of the clinicians have been working for long time, but you may not be exposed to post-op oral cancer cases"

P7 (Specialist, HUS)

.."I think this is one of the good ways to go about because it helps the clinician to conduct the session in a very systematic way, so you don"t miss anything.."

P1 (Specialist, QEH)

"Because sometimes, we won"teven go and check on these things, unless patient complaint. But, with this guide, this is like all the prompt list*. Then, we want more, we ask the patient."*

P16 (DO, HSJ)

"by having this prompt list*, it is not only helps the patient to ask what they want, it also helps the clinicians to see the* prompt list *and also to notify the points they have missed out to ask the patient"*

P6 (Specialist, HUS)

"I think the part is related to dental is quite helpful because sometimes we don"t get to ask in details, it is like a ting, ting, a reminder to ask more about whatever they experiences. Sometimes, actually, for sure, that is more than one thing, and then, when we asked, they only mentioned one."

P6 (Specialist, HUS)

"It is also a very good guide, not just for the patient, also for the clinicians as well. Sometimes, no matter how much you are experienced or how many years you put, the questionnaire you ask the patient, sometimes you can miss out."

P11 (Specialist, HSA)

"Like other days, we have so many appointments, so we tend to rush. And we forget to ask certain things. So, the prompt list *is good in a way that it helps us to remember there are things that we need to know and what we need to ask, what patient"s concern,*

P12 (DO, HAS)

e) PCI-H&N provides a glance of patients' general health state

PCI-H&N offers a full listed-items on post-op oral cancer patients' concerns that are related to HRQoL. Therefore, the clinicians were able to understand patients' state of health at a glance. Therefore, the clinicians will be able to provide a comprehensive patient management and a quality follow-up consultation.

"In terms of contents, because it is broad, a lot of the time, we only think about mouth. What concerns around the mouth and nothing else. We forget that there are other patient"s concerns. For example, like the patient just now, his mouth too dry or memory loss. Because we rarely ask. We will ask, do you have dry mouth? We know, we

immediately go into the oral cavity. We rarely ask how it affects their daily lives. Or does your shoulder hurt? Can they turn their neck? Things like that.

P9 (DO,HUS)

…" doctor sees the prompt list, maybe I ask question related to this, I believe it helps. "

"because it is more of, we try to understand you better and how the cancer affected you, that is why we need to know more, so that we can see whether we can help you in other ways. So far, I think patients have been very happy with it. "

P12 (DO,HSA)

.."then, we know, then we better prepared when we see this patient. We don"t, like, oh, this patient have social issue like this, some financial issue macam ini, clinical problem macam ini, so we have some sort of like, being prepared for that.."

P15 (Specialist, HSJ)

f) PCI-H&N is able to provide a holistic patients' care approach to post-treatment oral cancer patients.

The PCI-H&N had been seen to support holistic patient approach as it covers all aspect related to patient health related quality of life which can be seen as more humanly rather than concentrating on clinical outcome improvements.

…" I think they are a bit more like supported as well, like you care more about them as a person instead of just patient."

P4 (DO, QEH)

.."because most of the time, we are more taking care about curative part."

P15 (Specialist, HSJ)

"And I think the patient is quite happy also, because someone is like taking care of them lah. Patients are very happy overall lah. Other than that, every time, we come and just check all those lymph nodes and intraoral, and the patients feel like, he just came for review"

P16 (DO, HSJ)

g) PCI-H&N promotes the multi-disciplinary team

PCI-H&N enable the clinicians to promote multidisciplinary team management by referring the patients to relevant units for further management. This can enhance holistic patient management. Cases that are beyond the speciality of a dentist should be referred to the expert in the specific field to manage for example under management of ear, nose and throat (ENT) or the psychiatrist.

"They have follow up with other departments. Like this lady, she has eye problem, hearing problem, so that is already under ENT. So, just make sure they follow up ."

P6 (Specialist, HUS)

"But, because after the surgery, the patient went into some forms of, psychiatric problems. Because even when you see him in the ward, that is why we referred him to psychiatrist. But, he is not under psychiatric care. At least we know he has that concern and he has psychiatric care, so we are hoping that they will also help to address that"

P6 (Specialist, HUS)

"Not all can be addressed by us. But, it may help facilitate referral to the respective departments."

P11 (Specialist, HSA)

h) PCI-H&N helps patients to identify their concerns.

The clinicians noticed that patients were more involved in the discussion as they realised that there were broader prospective in follow-up consultation. The patients could inquire other aspect due to oral cancer than just confined to oral cavity and cancer site. Since the prompt list covers all aspects of HRQoL, it was seen to meet patients‘ unmet needs and encourage on more open discussion with the clinicians and further promote shared-decision making.

"In terms of contents, because it is broad, a lot of the time, we only think about mouth. What concerns around the mouth and nothing else.

P7 (Specialist, HUS)

"if they see the prompt list and they see something, the topic that they believe they can ask, so that is why I think it helps them to bring out what they want to ask."

P10 (DO, HUS)

"Example like, patients had fear of cancer comes back which actually we don"t address."

P7 (Specialist, HUS)

i) PCI-H&N encourages patient empowerment

The prompt list enables patients to forward their concerns or worries to be discussed with the clinicians during the follow-up consultation. Most of the patients are unaware of the impact from the oral cancer treatment on them that can be discuss with their clinicians. The prompt list which listed all the post-treatment patients‘ concerns serves as a guide to assist the patients on the issues that they are unsure of.

… "the prompt list is in words if they see the prompt list and they see something, the topic that they believe they can ask, so that is why I think it helps them to bring out what they want to ask. Sometimes, the patients, they don"t know what to ask. They unsure. So, when they see the prompt list, they like..oh, this is something that.." I want to ask, so when they tick, and the doctor sees the prompt list, maybe I ask question related to this, I believe it helps."

P12 (DO,HSA)

"the prompt list, it helps for the patients to concentrate on the points that they believe that is affecting them, and it also, it quite comprehensive. Sometimes, patients who are unsure what to ask or they didn"t even think about it, then when we say the questionnaire, and they think about it, okay, there is something they can ask. So, we can treat the patient as a whole, even better. So, I think it is very useful to having the prompt list."

P6 (Specialist, HUS)

j) PCI-H&N could be useful for patients' self-assessment of their current well-being.

The prompt list was also seen to be used as an assessment aid of whether they were having any of the concerns. By not having any issues for the discussion or few concerns, they could know they are at a better condition. Hence, PCI-H&N is not just a prompt list to identify patients concerns but also as a patients' own reflection of their current condition.

"There are some issues to be raised, I think it is also a kind of like, how to say, like at the back of your mind, they are thinking, there are so many problems listed, oh I don‟t have this, I don‟t have this, I don‟t have this"

P3 (DO, QEH)

k) PCI-H&N provides added value during the patients' waiting time

The prompt list was viewed as an added value material while patients are waiting for their appointment session at the waiting area. It gives a chance to create awareness among the post-treatment oral cancer patients.

"Actually, if the borang, you give at the counter, because they have to wait also for them to be called inside, while waiting, it can be like a reading for them."

P6 (Specialist, HUS)

Based on the FGD, few verbatims arised as the barriers encountered during the implementation which need to be considered and overcome prior the PCI-H&N implemention (in either versions). Listed are the barriers encountered:

i) Implementing PCI-H&N among health personnel and patients is highly depended on individual acceptance

Acceptance in implementing PCI-H&N as a new procedure during the follow-up consultation will require a ―familiarisation phase" among health personnel for better understanding of its usage until they are a accustomed to it.

~~I~~ think they probably need short briefing. If they understand why or when to do it, I am sure they can implement fast."

P12 (DO, HSA)

Similarly, patients were also reluctant to participate in this study but after been briefed, they complied. It is also depends on the clinicians whether to conduct the PCI-H&N before the consultation as this is an important aspect to ensure sustainability.

"So far, patients are cotreatment because most of the oral cancer patient post-op, they are keep coming for check-ups, they are cotreatment and compliant. Of course, initially, they are like, what is this all about. But, other than that, once we have explained everything, then they are actually quite compliant, rather than they are not happy lah to fill out this thing, dia dah okay dah, dia actually compliant."

P12 (DO, HSA)

ii) Administrating PCI-H&N requires additional human resource.

There were two different views identified in this present study. Firstly, the possibility of implementing PCI-H&N as a routine procedure does not require additional human resources at the registration counter as it only requires them to provide the PCI-H&N to the patients.

"It is just more on the counter people, the one who register. Just extra work for them, they have to pass to them the form." "I think it is mild, it is just an extra work."

P7 (Specialist,HUS)

"Tak ada rasa bagi beban sangat."(Assistant)

" Kalau just nak bagi ready the PC, I think it is okay. Tak ada masalah.

Translated:"it"snot so much a burden. Not a problem to get the website ready for patients use".

P13 (DSA,HSA)

On the other hand, some facilities need additional support staff to conduct the PCI-H&N and to be more organised in post-treatment oral cancer patient management.

"Do you think you need extra assistance just to assist in doing the prompt list? Yes"

P13 (DSA,HSA)

"One problem here, we have a bit short of manpower, resources. If we have a little bit more proper. We need somebody who dedicate, somebody extra. And we need a coordinator who is very strict."

P15 (Specialist,HSJ)

iii) Inadequate supportive infrastructure: IT equipment and interrupted internet connection

Implementation of the computerised web-based version had experienced difficulties due to absence of IT equipment and unstable internet connection at their facilities.

..."because our hospital is, we don't have proper IT equipment"

"The printing ada masalah sikit lah. But, this morning, the problem is more on the internet problem."

Translated: there"s problem in the prtinting process, but this morning the problem was more on the internet connection problem".

P7 (Specialist,HUS)

..”web-based ini, it depends on how strong is your internet reception as well..”

P1 (Specialist, QEH)

Touch screen so far, it is okay but sometimes, due to the connection, also has some problems. Or else, due to the connection lah. Sometimes, patients answering half way, and then no connection

P16 (DO, HSJ)

iv) PCI-H&N was available in two languages only (Malay and English)

This study only used PCI-H&N in two translated language; Bahasa and English. Through observations, this barrier occurred among the elderly patients especially in Sabah and Sarawak as they have different dialect and from lower education or no formal

“Yes, language version is one. But, you need proper translation. “

P6 (Specialist, HUS)

“Yes, for Mandarin. Even, sometimes we have Iban speaking, so there is no non BM and English languages”

P13 (DSA, HSA)

.."I think a lot of the patients, because we are talking about cancer patients involved mid age over, and some of them do not have formal education also, sometimes the dialect, they need some helps with it also.."

P3 (DO, QEH)

v) PCI-H&N may prolong follow-up consultation time.

Generally, the clinicians admitted that due to time constraints, they were unable to spend adequate time with their patients during the follow-up consultation. The used of PCI-H&N was viewed to increase the consultation time. As for some OMFS who do not have specific oral cancer follow-up day, they would prefer to conduct the PCI-H&N in different session as more time can be allocated for the patients.

"I think, just more on our parts, we have a lot of patients, we found we cannot spend enough time."

P7 (Specialist, HUS)

…"because you have the prompt list and we can follow. But, maybe that would make our consultation time longer.."

P9 (DO, HUS)

..we might need another session or specific session to conduct this study or this type of consultation. So, for us, I think it will a bit difficult because we don"t have enough time.

P16 (DO, HSJ

4.10.3 Suggestion for improvement of PCI-H&N implementation.

During the implementation of PCI-H&N, the clinicians and the assistants encountered few possible improvisation that could be done in order to suits in their process flow. The suggestion as describe below:

i. Option of PCI-H&N to be completed in the surgery room

Some users prefer PCI-H&N to be completed once the patient‘s been called into the surgery room. It is expected to reduce burden of the counter staff and to avoid wrongly identified post-treatment oral cancer patients.

"One thing in our clinic, we don"thave khas one day for oral cancer sahaja. So, it is a mixed. So, the counter people may not know this patient is actually oral cancer patient. So, we cannot give at the counter. Maybe, once inside,"…

P12 (DO, HSA)

"Actually, we can change, we can put a mark dekat card, this is oral cancer patient. We probably can improve it, by marking at our card, so the clerk who register will know this is the oral cancer and shares the prompt list."

P12 (DO, HSA)

"Maybe in the surgery room, because if the patient is already being given a follow up, then it is the duty of the officers and the assistants who keep the appointments to deliver. As soon as the card comes in, the DSA would give."

P7 (Specialist, HUS)

"But, if you give at the counter, that might be an issue there as well. Not being given, given to the wrong patient, mix up the cards"….

P7 (Specialist, HUS)

ii. PCI-H&N to be completed at home

There were also suggestions for the patients to complete the prompt list at home prior to their following appointment but they foresee that the patients might leave it at home on the appointment day.

~~"~~Sometimes, three and four months away. So, we gave them early, so, bila dia datang, dia lupa nak bawa. Or they fill out very earlier on, it is not the concern at the current time, at the point they are coming"…

Translated: Sometimes, three and four months away, when we give them ahead to be completed

P9 (DO, HUS)

"I think the prompt list is helpful because we can give to the patient before they are come"

P12 (DO, HSA)

iii. Prioritising patient's concerns by a scoring system

Scoring system can help the clinicians to identify patients' priority of concerns in order to optimise the follow-up consultation session without causing a delay on other patients' appointment slots and to overcome the time constraints faced in normal clinic set-up.

"Yes, to put somewhere like even though they tick foe example swallowing problem, how bad is it? Scoring?"

P6 (DO, HUS)

"Like, macam patient tadi, dia cakap, dia ada masalah menelan, tetapi tak ada lah teruk sangat. Kadang-kadang. So, ada certain things tu, kadang-kadang, not all the time. Because that is in the prompt list, and they do have it, and they tick. But then, we will be able to see whether that is a big major concern or small minor concern"…

Translated: „For exanple, there was a patient concern on swallowing problem but was not that bad, only sometimes. So there are certain patients" concerns which are not as serious issue but since it was listed in the prompt list, patients tend to „tick" on that concern as well".

P6 (DO, HUS)

…"concern that really bugging them. We really want to see whether we can help them. But, they may be bothered by small concerns, but we can advise, anything like that"…

P12 (DO, HSA)

CHAPTER 5: DISCUSSION

This chapter first discusses the study‘s strengths and limitations, followed by the response rate, the patients‘ profile, and the findings by comparing the present study with other similar studies. It is hoped that it can provide an added value to the clinicians managing oral cancer cases in Malaysia in achieving optimal quality of care. However, the discussion should be interpreted within the limitations of the study.

5.1 Strengths and limitations of this study

To date, this is the first study conducted to determine post-treatment oral cancer patients‘ concerns and its relationship with patients‘ clinical characteristics, HRQoL, psychological distress and patient satisfaction during their follow-ups. The strengths and limitations of this study are discussed in the following sections.

5.1.1 Study strengths

i. Multicentre study sites

This study involved five MOH tertiary hospital-based OMFS clinics and one teaching hospital OMFS specifically for oral cancer management in Peninsular Malaysia, Sabah, and Sarawak. Multiple study sites are intended to represent patient variation in terms of ethnicity habits and practices in Malaysia (Ghani, Razak, et al., 2019; Maling, Doss, & Low, 2018). Thus, the outcomes interpreted in this study is deemed to be reflective of the post-treatment oral cancer population throughout the country. Multicentre study sites gives more advantages than collecting data from one site. It increase variability of patients‘ recruitment from various background and will generate more meaningful results and could suggest beneficial effects (Harden & Friede, 2018).

ii. Pragmatic RCT study design

The sample was drawn from a pragmatic RCT (*p*RCT) study of PCI-H&N which facilitated data collection under real circumstances as applied at the selected OMFS clinics as study sites (Dickinson et al., 2015; Haynes, Sackett, Guyatt & Tugwell, 2006). The post-treatment oral cancer follow-up management varied according to each clinical site to suit the work routine of the clinicians and patients‘ follow-up interval.

5.1.2 Study limitations

i. Sample size

The first limitation of this study was the small sample size, although this might be indicative of the low oral cancer incidence in Malaysia. Other similar studies had also obtained small sample sizes (Aguilar et al., 2017; Hatta et al., 2014; Jungerman et al., 2017; Roick, Danker, Dietz, Papsdorf, & Singer, 2020).

During the eight months duration of the present study, only 123 post-treatment oral cancer patients presented at the six study sites. The total was less than the expected sample size calculated earlier (n=192). This sample size limitation was unforeseen at the time of sample size estimation calculation. There was no reliable source available on the number of post-treatment oral cancer patients who were actively under follow-ups as a point of reference for the sample size estimation calculation. The required sample size was needed to reject a type 1 error (Das, Mitra, & Mandal, 2016). The assumption was that the expected sample size of 192 patients was achievable by conducting the study at the main referral centres of oral cancer management. However, several reasons might have contributed to this small size.

Patients‘ compliance in attending their appointments are highly crucial in the patients‘ recruitment. The present study recruited patients from among those who presented for their follow-up consultation. Thus, the number of patients enrolled in this study depended on the number of patients who presented on their appointment day during the data collection period. Therefore, the number of recruited patients was unpredictable. Most patients attending the OMFS clinics were of the older age groups who depended on their carers or children to bring them to the clinic; and thus, many had missed some of their appointments. Other unavailable patients included those who were continuing their follow-up appointments back at their district hospitals instead of the tertiary centres. The study sites are the referral centres for oral cancer management in Malaysia, and some patients who resided far away and from other districts were initially referred to these centres for diagnosis and treatment purposes. However, once completed, they were given the option of continuing their follow-up appointments at their primary district hospitals, mainly due to logistic reasons, especially in Sabah and Sarawak.

Another reason for the small sample size is the time constriction. Data collection period could not be extended more than eight months due to the time allocated to complete the study. Although eight months seemed like a long period to be able to collect enough participants, the frequency of follow-up sessions varied between study sites. Some OMFS clinics have monthly reviews basis while others have fortnightly reviews; only one study site did reviews weekly. Thus, the frequency of follow-up appointment days in each facility partly affected the number of participants recruited.

The most pivotal reason might be the withdrawal of one of the selected proposed study sites (Tengku Ampuan Rahimah Hospital, Klang, Selangor (HTAR)) from participating in the present study during the data collection period. HTAR has one of the highest numbers of oral cancer cases management in Malaysia with scheduled twice weekly follow-up clinic sessions. The head of the department, HTAR, decided not to participate in this present study because there was an ongoing data collection for a different study involving the same study population. His decision was made in the best interest of the patients to avoid imposing an extra burden on the patients. Therefore, the UM OMFS was then included in this study as a substitute to increase the number of samples.

The post hoc power analysis achieved from the main study of *p*RCT was 68.2% (with given n=85, partial R^2= 0.095, effect size=0.105 at 0.05 significant level, test family: F-test, statistical test: multiple linear regression).

The final sample size distributed in each study groups was 55 patients (44.7%) for the paper version, 30 (24.4%) patients for the computerised web-based version, and 38 patients (30.9%) for the control group with the ratio of 6:3:4, respectively. The PCI-H&N paper version sample was higher in ratio due to the unexpected physical and technical problems encountered during data collection. At some study sites, the internet connection problem led to the reassignment of the computerised web-based version participants to the paper version. The purpose of the reassignment was to avoid losing the study sample and/ or having the patients wait too long for their consultation session.

ii. Self-reported questionnaire

Another primary limitation of this study is using self-reported questionnaires to obtain the data. A self-reported questionnaire is highly dependent on the participants‘ honesty in answering the questions (Althubaiti, 2016). Self-reported data could exaggerate the input, leading to under or over-reporting. Furthermore, proxy-assisted completion of questionnaires may have led to information bias as the proxies may have had different interpretation or understanding of the patients' answers.

Patients were also required to answer two post-consultation questionnaires at home and mail it back within a month using the self-addressed envelope provided. The different setting of completing the questionnaires could have influenced the way the patients answered the questionnaires. Different settings such as completing the questionnaires at home, or within the hospital environment, and the questionnaire administration mode (face-to-face interview performed by proxy or self-administered) can affect the questionnaire output (Bowling, 2005).

iii. Response bias

All health personnel who were involved in this study had a prior training session at each study site before the conduct of the present study. However, throughout the data collection period, there was no monitoring of the dental assistants (DSA) who were assisting the patients (upon request by patients). Thus, the DSA may have influenced the patients in the answers given. The patients may have responded according to what they thought the interviewer wanted to hear as the person who assisted them was a hospital staff, and they have been worried that their answers might influence their treatment or management. This assistance may have induced response bias. In the future, to avoid a response bias and elicit honest answers from patients, the assistants should be individuals with no conflict of interest to avoid the Hawthorne effect.

This question prompt list was used for the first time by patients and some health personnel involved in this study. Therefore, patients may have selected the concerns based on what they had encountered throughout the duration after treatment and not precisely the concerns they experienced for the previous seven days.

iv. No blinding in randomisation

Blinding is one of the approaches to ensure study rigour and internal validity in an RCT study design. However, some studies could not conduct the ‗blinding' as it was not appropriate in a pragmatic RCT study (Hotopf, 2002). As in the present study, ‗blinding' of the patients' study group could not be conducted as the two versions of PCI-H&N could be recognised by their different physical forms.

v. The high number of non-responsive sample

Respondents at one-month post-consultation were only 63.4% (n= 78). The high number of non-respondents (36.6%) contributed to insufficient data that may have led to information bias for comparison before and after a study was conducted. The present study incorporated various sociodemographic and cancer characteristics of post-treatment oral cancer patients. A comparison may not be tenable given the high number of non-respondents.

Therefore, although the study findings may be of added value to clinicians for improving their management of their post-treatment oral cancer patients, the outcomes should be interpreted within the study limitations.

5.2 Response rate

All eligible post-treatment oral cancer patients who were present on their follow-up appointments were included in this study. The response rate was quite high, with nearly 88% at baseline and the completion rate was at a moderate percentage (63.4%) among those who returned their post-consultation questionnaires. The number of patients recruited was lower than the expected sample size (n=192). Thus, a few initiatives were taken to increase the follow-up response rate. It was strongly impressed on the participants about the importance of their one-month feedback; phone calls were done to remind the patients of the due date for post-consultation questionnaires; and, monetary honorarium was also given to participants as an incentive and as a token of appreciation. Besides that, post-consultation feedback was also conducted through phone calls for those who needed assistance. However, as mentioned in another study, the incentives provided may not have affected the numbers of the response rate (Ryu, Couper, & Marans, 2006). Therefore, with the final sample size obtained in this three-armed *p*RCT, the post hoc power analysis achieved was 62.5% with effect size 0.36 at 0.05 significant level.

The three study groups were not equally distributed (paper: computer web-based: control; 55:30:38), with more in the paper version group. One of the reasons was the unreliable internet connection at the study sites. Patients who were initially assigned to the computerised web-based version were automatically changed to paper version when internet problems occurred so as not to lose them (as there was already a sample size problem). Another reason was partly due to the locations of the study. The multicentre study sites creates unbalanced patients allocation as the flow of the patients‘ recruitment were not continuously recruited in the same order (Harden & Friede, 2018). This situation led to the unbalanced patients‘ ratio in each of the three study groups. Unbalanced treatment allocation can result.

5.3 Patients' sociodemographic background

There was no significant difference in terms of patients‘ sociodemographic background across the three study groups. The majority of respondents were Malay, and females constituted nearly 60% in this study, although many previous studies reported higher incidence among the males (Bray et al., 2018; Cheong et al., 2017). Previous studies also reported that Indian ethnicity, especially the Indian females, and the indigenous ethnicity of Sabah and Sarawak were observed as the high-risk group for oral cancer in Malaysia (Azizah, Nor Saleha, Noor Hashimah, Asmah, & Mastulu, 2016; Ghani, Razak, et al., 2019). In contrast, post-treatment oral cancer patients of Indian ethnicity constituted the least in the present study. This findings concurs with the 2019 Profiling of Oral Cancer Cases in Malaysia whereby Malays (n=29) were higher compared to Indians (n=11) and Chinese (n=4) (OHP committee, 2020).

The patients in this study were mostly between 51 – 65 years old (41.5%) with a mean age of 60.1 (± 12.5) years old. In contrast, the mean age reported among oral cancer patients by Ghani, Razak, et al. (2019) was much younger with a mean age of 53.5±17.3 years old with slightly more than half of the cases (52.1%) aged more than 60 years old. Married patients were highly represented (68.3%), and a majority had some form of education, with only 13% having ‗no formal' education. This finding was supported by most previous local studies that reported a higher incidence among lower education level and lower socioeconomic background (Cheong et al., 2017; Doss et al., 2011).

5.4 Patients' cancer characteristics

The tongue remains as the highly reported oral cancer site (Balasundram et al., 2012; Bray et al., 2018; Ghantous & Abu, 2017). Studies also reported that a higher probability of oral cancer at the posterior lateral border of the tongue is related to late cancer staging (Crispian Scully & Bagan, 2010). Apart from that, increasing cases of anterior tongue cancers affecting the younger age patient group (Ghantous & Abu, 2017) has been previously noted, and this incidence needs to be addressed for early detection and prevention. A recent study had reported a relationship between ethnicity and cancer sites whereby 76.3% of Chinese were reported to have common occurrence on the tongue or floor of the mouth whereas, 70.8% Indians had gingivae/ buccal mucosa cancer. In contrast, the Malays and Indigenous ethnicities had almost equal site distribution (Ghani, Ramanathan, et al., 2019).

Oral cancer treatment can be debilitating as it involves surgery, radiotherapy, chemotherapy, or a combination of those treatment modalities which depends on the cancer characteristic (Dionne, Warnakulasuriya, Binti Zain, & Cheong, 2015). More than half of the patients in this study were in stage I and II at the time of diagnosis compared to most studies which reported more of late-stage oral cancer (stage III and IV) (Balasundram et al., 2012; Cheong et al., 2017; J. G. Doss et al., 2017a). The variation of oral cancer treatments depends on the cancer staging and other cancer characteristics (lymph nodes involvement, metastasis to other parts of organ and cancer sites). Nearly half of the patients had received surgery only, followed by combination treatment (surgical and adjuvant radiotherapy or chemotherapy treatment). As the majority of patients were diagnosed at an early cancer stage, more patients received the treatment mode of surgery only; as the combination treatment is most preferred for advanced cancer stage (Edge et al., 2010; NCCN, 2019).

The follow-up interval of oral cancer patients depends on the patients‘ time after treatment was completed. A regular and shorter interval of time (monthly review) is indicated for post-treatment patients who had completed treatment in one year with a subsequent follow-up interval until five years (NCCN, 2019). Median time after treatment completed was 2.0 years (IQR: 1.0 – 4.0) reflecting that the patients were mostly those who had completed treatment in recent years as the follow-up reviews were more regular (monthly basis). Patients should be provided with access to quality oral cancer care and continuous follow-up reviews which could lead to life-long improvement of post-treatment oral cancer patients (Samim, Epstein, Zumsteg, Ho, & Barasch, 2016; Thavarool et al., 2019).

5.5 Post-treatment oral cancer patients' concerns

The number of concerns selected in this study was lower compared to the latest PCI variation study with a median (IQR) of five (2-10) items and a range of zero to 48 items (Rogers et al., 2019). Nearly 50% of the patients in the same study had selected six or more concerns (Rogers et al., 2019), whereas another study reported 41% oral cancer patients within one year of post-treatment with high DT (> level 5). These findings may imply that Malaysian post-treatment oral cancer patients had better health outcomes after completing treatment with lower impact on their daily routines. Nevertheless, it could also be reflective of our customs of conventional upbringing that did not encourage sharing our worries with others, especially outsiders.

Almost 42% of post-treatment patients (of five years and more) in the present study had more than four concerns, possibly due to the cumulative effect and permanent disability related to their disease and the treatment received (Kanatas et al., 2013; Crispian Scully & Bagan, 2010). As such, from the point of diagnosis and throughout cancer treatment and post-treatment, using a prompt list, for example, the Patient Concerns Inventory, that assists cancer patients in identifying their concerns during the consultation session and seek relevant information would be beneficial (Byrne & Rogers, 2017).

Concerns selected were commonly from the three PCI-H&N domains, i.e. physical status, emotional status, and treatment-related, which differed very slightly only from the findings of a previous local study. The study observed that patients frequently raised issues concerning physical status (94.4%), followed by emotional status (31.9%), and personal function concerns (30.6%) (Hatta, Doss & Rogers, 2014).

Most of the patients who had undergone surgical and adjuvant treatment of radiotherapy, with or without chemotherapy, selected the physical status domain with a higher number of concerns. This outcome was expected as post-treatment involved the removal of cancer affected tissues that caused physical distortions, and in some cases, caused a permanent impairment (Reichart & Way, 2006). The extensive surgical resection involved flap reconstruction, neck dissection and with adjunct radiotherapy/chemotherapy post-treatment that was also associated with patients‘ worsened QoL, which more often than not returned to pre-treatment levels (at baseline) by one year after treatment had completed (Rathod et al., 2015). Daily physical and social functioning were mostly affected after an operation, especially swallowing, chewing/eating, saliva issue, taste, and aesthetics (Rathod et al., 2015). With more complex treatment, the impact on patients‘ physical disfigurement and dysfunction affected patients‘ emotional status and further disrupted their daily routines (Good et al., 2014; Rathod et al., 2015).

‗Fear of cancer coming back‘ was mostly selected among the patients in this study and it concurs with other similar studies (Ghazali et al., 2013; Rogers, 2010; Rogers et al., 2019; Rogers, Scott, Lowe, Ozakinci, & Humphris, 2010). This finding implies that post-treatment oral cancer patients across different countries, regardless of ethnicity and religion, are potentially at risk of mental health issues such as ‗fear of recurrence‘, ‗distress‘, ‗anxiety‘, and ‗depression (Lu et al., 2016). In a previous qualitative study, it was revealed that patients were afraid or anxious about uncertainty in the future, death, costs of treatment, and operative procedures when they heard about their diagnosis (Jagannathan & Juvva, 2016). It was reported that approximately 20% of post-treatment oral cancer patients experienced a recurrence and of this, 90% of the patients discovered the cancer in the first two years post-treatment (Kissun et al., 2006).

A local study by Hatta et al. (2014) did not reveal similar findings as above. Their study reported that nearly 50% of patients had selected concerns on ‗chewing/eating‘ (48.6%) followed by ‗pain in head and neck‘ (43.1%); both concerns from the physical status domain. As highlighted in many other studies (Aguilar et al., 2017; Hatta, Doss & Rogers, 2014; Rogers et al., 2019), the top five concerns in the present study were much related to dental issues such as ‗dental health‘, ‗chewing‘, ‗dry mouth‘, ‗sore mouth‘, and ‗swallowing‘. Although differences in the ranking order of concerns were noted in comparison with recent findings by Rogers et al. (2019), dental health and oral functions constituted the six most frequent patient concerns, which are very much related to the early phase of post-treatment. These concerns are mostly managed by the multidisciplinary dental team. As such, the importance of identifying and addressing patients‘ dental health concerns is undeniable. There is a need to have a tool to highlight these concerns to achieve patients‘ satisfaction and positive outcomes specifically on patients‘ HRQoL, psychological distress and clinical outcomes (Shunmugasundaram et al., 2019)

The least of patients‘ reported concerns included vomiting/sickness, carers, relationship, spiritual/religious aspects, and mood swings, which the patients probably were able to cope with and did not affect their routine life. Patients also did not highlight some issues such as sexuality/intimacy or lifestyles habits (smoking/alcohol). Presumably, these issues are more private topics and perhaps patients felt it is inappropriate to discuss with clinicians (Rogers et al., 2009; Rogers et al., 2015). It could also be possible that their clinicians did not address issues on intimacy in relationships (Hautamäki, Miettinen, Kellokumpu-Lehtinen, Aalto, & Lehto, 2007; Ussher et al., 2013).

Two versions of PCI-H&N were used in this study to compare and assess its feasibility to be part of the routine follow-up consultation. The present study found concern namely ‗dry mouth‘, ‗taste‘, ‗coughing‘, and ‗coping‘ had a significant difference between the two versions. However, as for the clinicians, these findings had no clinical impact since the content and function of both versions are the same (Scott, Ghazali, Lowe, Bekiroglu, & Rogers, 2013).

5.6 Health-related quality of life among post-treatment oral cancer patients during follow-up consultation

At baseline, the total score for HNS domain was at the lower end from its range (0-36) whereas other domains showed a total score of the upper end. Questions addressing the HNS domain are related to oral functions such as eating, chewing, swallowing, voice, speech, breathing, aesthetic appearance, and whether they have dry mouth. Hence, it can support the findings regarding dental-related issues selected by the patients in this study, such as dental health, chewing, dry mouth, sore mouth, and swallowing.

In recent years, younger age patients are more at risk of the negative impact of HRQoL compared to older patients (Doss et al., 2017). Younger age patients were more affected in terms of emotional status domain while the older age patients were more affected in their physical functioning by 12 months post-treatment (So et al., 2012).

In contrast, the present study did not find any significant difference in HRQoL changes from baseline to 1-month time among different age groups of patients. This result concurs with a study that observed significant changes in HRQoL only in a period of three to six months of continuous follow-ups and not in a short period (Wiklund et al., 1990). A systematic review reported a similar finding of non-significant difference as reported in the present study whereby no changes were observed between baseline and at one month time but only at 12-month post-treatment regardless of sociodemographic background (So et al., 2012). Hence, it explained the non-significant changes observed among different age groups patients‘ HRQoL at one-month post-consultation in the present study.

On the other hand, a slightly higher Malaysian-added questions (MAQ) domain score compared to the baseline score was seen at the one-month post-consultation among the PCI-H&N users even though it was not statistically significant. MAQ consists of eight questions but only seven questions were included for the total MAQ scoring; the question on betel quid chewing habit was excluded. These questions are related to patients‘ spiritual aspects that were influenced by oral cancer, difficulty/limited mouth opening, stiffness or limited movement of their shoulders, body numbness, lack of appetite for food, bleeding or ulcers in the mouth, and food stagnation in the mouth and have difficulty in maintaining oral hygiene. This study observed non-significant slightly higher scores ‗on body numbness‘ and ‗food stagnation in the mouth and having difficulty in maintaining oral hygiene‘. It is common for post-treatment oral cancer patients, especially those who had undergone surgery and chemotherapy treatment, to experience numbness which may progress to normal sensation with time (Pongthavornkamol, Lekdamrongkul, Pinsuntorn, & Molassiotis, 2019). The numbness might occur if nerves were bruised, and muscles were removed during the surgery. Relatively, along with the surgical removal of the cancer tissue, the feeling of numbness also may affect patients‘ ability to chew/eat as paraesthesia makes patients unable to control their oral cavity muscles (e.g. tongue and buccal mucosa) during mastication. The condition caused food stagnation and further compromised patients‘ oral hygiene (Dineen, Collazo, & MacCarthy, 2019). It also concurs with a systematic review study whereby most studies showed improvements in HRQoL by 12 months post-treatment, however there were few outstanding issues which still persist and remained prolonged with time namely physical functioning, fatigue, xerostomia and sticky saliva that give impact to patients‘ HRQoL. Therefore, these issues should be one of the important aspects that should be assessed and monitored during patients‘ follow-ups.

A previous local longitudinal study observed a significant deterioration of patients‘ HRQoL at one-month post-treatment regardless of patients‘ cancer staging, and a significant difference with the treatment modalities (Doss et al., 2017). The impact further worsened at 3-months onwards among patients who received a combination mode of oral cancer treatment, specifically among those with late stage of cancer (Doss et al., 2017). The present study observed a significant association between patients‘ HRQoL and oral cancer staging ($p<0.05$); however, there was no difference observed between patients‘ HRQoL and the types of treatment received. Lower impact on patients‘ HRQoL was strongly associated with those in one-month to one-year post-treatment phase. This outcome was expected as patients were at an early phase of their recovering process from treatment besides adapting to their new life as cancer survivors (Doss et al., 2017; Murphy et al., 2007).

The HRQoL challenges faced by post-treatment oral cancer patients do have an impact on their psychological distress. Patients with lower quality of life have significantly poorer psychological well-being that can cause difficulties in performing daily functions (Shiraz et al., 2014). This is discussed in the following section.

5.7 Psychological distress level among post-treatment oral cancer patients during follow-up consultations.

Approximately one-fifths of the present study sample perceived themselves as being at risk of psychological stress (DT ≥ 4), and only one patient claimed to be extremely stressful (DT level=10). A higher proportion of psychological distress was observed among the westerners whereby Ghazali, Roe, Lowe, Tandon, Jones, Brown, et al. (2017) reported that 36% (n= 62/270) of post-treatment head and neck cancer patients had significant distress level of DT= ≥ 4. An earlier study by Wells et al. (2015) had found that one-third of oral cancer survivors had moderate/severe levels of distress with three-quarter having at least one unmet need.

No differences were observed in psychological distress in terms of sociodemographic background (in sex, marital status, employment status, comorbid of other diseases, received surgery treatment, radiotherapy and hormonal therapy, and current risk associated habits: cigarette, alcohol, and betel nut use) and this concurs with a study conducted by Chiou et al. (2016).

This study found that psychological distress was associated with patients‘ oral cancer staging and HRQoL. Psychological distress was identified in nearly half of the cancer survivors in a study conducted in Southeast Asia (ACTION Study Group, 2017). In the study, it was mostly observed among those at an advanced cancer stage at diagnosis and older patients while males with low HRQoL scores and at advanced cancer stage at diagnosis (stage III and IV) was the strongest independent predictor of high psychological distress level (ACTION Study Group, 2017). However, in the present study, post-treatment oral cancer patients at risk of psychological distress were among those at early cancer stage (stage I and II). Previous studies found that patients were at risk of psychological distress if they had poor health-related quality of life, received radiotherapy, and had longer consultation times in clinic (Ghazali, Roe, Lowe, Tandon, Jones, Brown, et al., 2017; ACTION Study Group, 2017; Harding & Moss, 2018). However, this study did not reveal a positive psychological change with the _time after treatment completed' (Harding & Moss, 2018) when most other similar studies reported that post-treatment oral cancer patients might experience prolonged psychological distress even after five years of treatment (Pocobelli et al., 2019).

Head and neck cancer has a high impact on the daily aspects of life, which often relate to physical, emotional, and functional aspects (Frampton, 2001; van der Meulen, May, Koole, & Ros, 2018). As observed in the present study, physical and emotional concerns were strongly related to psychological distress among post-treatment oral cancer patients. The presence of psychological distress among oral cancer patients is frequently undetected by their clinicians. In a different study, they found that more than 80% of the head and neck cancer patients were unaware of their psychological distress condition and, thereforem , did not seek for any psychiatric or psychological treatment (n=112/137 patients) (Chiou et al., 2016; Krebber, Jansen, Cuijpers, Leemans, & Verdonck-de Leeuw, 2016). Untreated psychological distress could induce negative post-treatment outcomes specifically on patients' HRQoL and clinical aspects (Chiou et al., 2016). In addition, psychological distress can also lead to low compliance with follow-up appointments, lost hope, and may lead to higher suicide risk (Fang et al., 2014). Hence, it is crucial to identify distress among oral cancer patients for timely intervention by referring to psychologists for further management.

Studies have shown that post-treatment oral cancer patients are at risk of mental health issues such as distress, anxiety, depression, and fear of recurrence (stronger association), which can be a prolonged impact from the disease and its treatment (Lu et al., 2016; Riba et al., 2019). Majority of unmet needs among post-treatment oral cancer patients were concerns on psychological issues (emotional status), for example, fear of recurrence, sadness, anxiety and depression that showed significant patients‘ distress level (Ghazali, Roe, Lowe, Tandon, Jones, Brown, et al., 2017; Henry et al., 2014). Similarly, the most highly selected concern among the population in the present study was ‗fear of cancer coming back‘, which was one of the specific concerns under the emotional status domain. Likewise, of the listed problem items, ‗worry‘ was the most highly selected by patients in the present study followed by ‗fatigue‘, ‗appearance‘, ‗sadness‘, and ‗insurance/financial problems‘. Least of their problems were ‗spiritual/religious concerns‘ and ‗diarrhoea‘. A great number of head and neck cancer patients with underlying psychological problems were not assessed and addressed during their routine follow-up as it is not the normal practice. The most selected problem item, ‗worry‘, was consistent with a study conducted by VanHoose et al. (2015) whereby patients who were at risk of psychological distress were five times more likely to endorse concerns related to ‗worry‘ as a possible problem to be related to their distress. Other concerns such as ‗sleep‘ (n= 47.6%), ‗fears‘ (n= 47.6%), ‗nervousness‘ (n=47.6%), ‗pain‘ (n=46.9%), and ‗financial problems‘ (n=38.9%) were most frequently endorsed by those in the at-risk group (DT $\geq$ 4) (VanHoose et al., 2015). Although both studies were not similar in specific concerns, however, they shared the same problem domains: practical problems, emotional problems, and physical problems, which showed to be highly related to patients‘ psychological distress. A higher proportion of patients being at-risk of psychological distress (DT $\geq$ 4), reflected in their selected problem items (‗worry‘) and PCI-H&N concerns (‗recurrence/

fear of cancer coming back‘) which if left unaddressed could lead to patient burnout in the long term (Frampton, 2001).

In terms of the problems listed in the DT screening tool, a very minimal positive changes were observed among the PCI-H&N study groups compared to the control at one-month post-consultation. Selected problems on non-dental related items such as fatigue, tingling at hands/feet, and insurance/financial problems showed a significant change of improvement at one-month post-consultation. This outcome suggests that these were probably short-term issues which patients were able to accept and adapt to while other issues required a longer period to cope with. As for the financial aspects, treatments were conducted in a government and a teaching university hospital in which the treatment fees were either heavily subsidised by the government or low semi-privatisation charges by education institutions that could ease patients‘ burden at a shorter time (Yu, Whynes, & Sach, 2008).

5.8 Patients’ satisfaction with the follow-up consultation.

Patients‘ satisfaction with the follow-up consultation is subject to their expectation of whether their clinicians allow them to express and share their concerns or worries during the consultation and allow them to be part of the decision making. Patients in the present study showed no significant difference in satisfaction between the study groups. Almost all patients were satisfied with their consultations. They agreed that the clinicians had allowed them to expressed their concerns openly, allocated enough time to discuss patients‘ issues, gave clear explanations, involved the patients in the decision making and referred the patients to other units for further management as required.

Follow-up consultation that is focused on individual patients‛ needs may help to address patients‛ unmet needs. Feedback on patients‛ satisfaction with the consultation may help clinicians to relate it to potential barriers involving (i) clinicians behaviour, (ii) environment of the consultation, and (iii) legitimacy barriers (Brandes et al., 2015). A study conducted by Fingeret et al. (2012) reported that patient dissatisfaction were related to ‗unmet informational needs‛ which included: (i) information provided on the degree of scarring/disfigurement to be expected after surgery; (ii) information on radiation treatment effect on patients‛ physical appearance, and (iii) on potential effects of chemotherapy on physical appearance. In addition, the dissatisfaction with the follow-up consultation was associated with time since diagnosis and patients‛ age, whereby higher levels of dissatisfaction were among the younger patients and at one year post-treatment (surgery) (Fingeret et al., 2012).

5.9 Association between patient's concerns and study outcomes

This section discusses the association and possible predictors between PCI-H&N items (in terms of the number of concerns selected, domain, and specific concerns) and study outcomes (patients‛ profile, HRQoL, psychological distress level, and satisfaction with the consultation) in addition to predictors of the outcomes mentioned earlier. The findings of this study could offer justification for the use of PCI-H&N in assessing outcomes of post-treatment oral cancer patients. All these are discussed according to the following sub-headings.

5.9.1 Association between patient's concerns and patients' profile

All the PCI-H&N concerns were not related to patients' profile except for the ‗time after treatment completed'. Although there was no significant association, it was observed that the elderly had a smaller number of concerns compared to the younger groups. A similar finding was also observed in the previous study by Doss et al. (2017). This finding is not surprising, as younger age patients have more commitments as they are at the peak of their life in terms of family, career, social life, and activities (Katz et al., 2011). With the mean age of 58.9 ± 12.8 years old of patients in the present study, most of these patients were married and with families. A systematic review reported that the elderly are more affected on physical functions and symptoms whereas younger patients focused more on emotional and role functions, and economic/financial concerns (So et al., 2012). A higher number of concerns ($\geq$ 6 items) were reported among female patients, late-stage patients, those who had radiotherapy and chemotherapy or chemotherapy only, and patients of 12 months post-diagnosis (Rogers et al., 2019).

The present study revealed a significant association between the number of PCI-H&N items selected and the ‗time after treatment completed' ($p<0.001$). This association is evident because oral cancer patients experience challenges from the time of diagnosis, through treatment, after treatment, and throughout their remaining life journey (Fang & Heckman, 2016). This study observed that a significantly high number of concerns was strongly associated with patients of ‗one-month to one-year post-treatment'. It concurs with a study conducted by Shunmugasundaram et al. (2019) whereby patients' unmet needs were influenced by time from treatment completed among those in the immediate post-treatment phase as opposed to long-term survivorship. Higher unmet needs suggest that patients have more concerns that they wish to discuss during the follow-up consultation.

On the other hand, fewer concerns were demonstrated among those who had completed treatment between three to five years in the present study. This difference could probably be that they had learned to adapt to their new situation by accepting and coping with the challenges to maintain social interaction (Ganzer et al., 2015). Some survivors (n=71%) also managed to resume their life as before treatment by returning to work within six months post-treatment (Verdonck-de Leeuw et al., 2010).

Oral cancer staging and treatment were not significantly associated with PCI-H&N domains. This finding contrasted with a systematic review conducted by Rathod et al. (2015), which revealed that patients who had surgical treatment with adjuvant radiation were associated with the physical domain concerns, especially dental related issues such as dryness of mouth, sticky saliva, and problems with mouth opening.

The present study observed that the time after oral cancer treatment completed was significantly associated with concerns regarding physical status, personal functions, and treatment-related domains. These three domains were highly associated with those of one-month until one-year post-treatment category. Patients in the early recovery phase of post-treatment in this study had mostly dental-related issues (eating, mouth opening), swelling, weight, ability to perform daily activities, cancer treatment-related issues, and health supplement or dietary concerns. In another study, the common issues at the early stage were fear of recurrence, dental health/teeth, taste, salivation, chewing, swallowing, mouth opening, fatigue, sleeping, speech, and pain (Rogers, 2010; Rogers et al., 2010). ‗Time after treatment completed' was observed to be also significantly related to cancer treatment-related issues (cancer treatment, regret about treatment, PEG tube, wound healing, health supplement and diet restriction). This fact is not uncommon as post-treatment oral cancer patients would have more issues related to the type of treatment received and its side effects. This finding concurs with a qualitative longitudinal study that reported post-treatment patients‘ concerns were mostly nutritional (Molassiotis & Rogers, 2012).

Post-treatment oral cancer patients had more issues or concerns at the early phase after completing treatment, especially within one year and this reduced in subsequent years. Molassiotis and Rogers (2012) reiterated this stating that challenges of adapting to their new life after treatment was one reason for this.

There are more impacts at the early phase of post-treatment, including the challenges of adapting to their new life after treatment (Molassiotis & Rogers, 2012). The present study showed that almost 42% of post-treatment patients (of more than five years) had more than four concerns possibly due to the cumulative effect and permanent disability related to oral cancer disease and the treatment received (Kanatas et al., 2013; Crispian Scully & Bagan, 2010).

5.9.2 Association between patient’s concerns and patients’ health-related quality of life

Head and neck cancer, including oral cancer, have a higher impact on patient‘s HRQoL compared to other cancer types. Many studies had revealed that patients‘ HRQoL deteriorated tremendously at the early stage of post-treatment and progressed towards baseline after one year (Bjordal et al., 2001; Doss et al., 2017; Molassiotis & Rogers, 2012; Murphy et al., 2007). It was also mentioned earlier in this chapter that patients‘ HRQoL improved after one-year post-treatment. Similarly, in the present study, we observed descending number of concerns raised among patients with better HRQoL score as also found in other similar studies (Ghazali et al., 2015; Vartanian, Rogers, & Kowalski, 2017). Rogers et al. (2019) had demonstrated that the number of PCI items selected was strongly associated with overall patients‘ QoL whereby one-quarter of the patients who had selected five to nine items had less than good overall QoL score.

PCI had gone through a few phases of improvements over the years and the patients‘ concerns had been grouped into structured domains for a clearer interpretation by the clinician (Ghazali et al., 2015; Hatta et al., 2014; Rogers et al., 2009). Hence, the selected concerns by patients can inevitably act as clues for clinicians to gauge their patient‘s HRQoL and health status without the use of validated HRQoL questionnaires as these are time-consuming and often require extra manpower, and can be impractical with the heavy patient workload in the clinics (Mead & Bower, 2000). As observed in the present study, physical status and personal functions domains were significantly associated with patients‘ HRQoL. This findings concur with a study by Aguilar et al. (2017) which found social well-being and physical status domains were frequently selected among post-treatment head and neck cancer patients.

Among the physical status and personal functions domains, ‗chewing/eating‘ was the most substantial concern that predicted patients‘ HRQoL. Given this strong association and similar findings of the impact of ‗chewing/eating‘ on HRQOL in another study (Aguilar et al., 2017; Cheong et al., 2017), this dental concern warrants special attention of clinicians and highlights the importance of multidisciplinary dental teams in its management. Patients‘ concerns, namely ‗appearance‘ and ‗ability to perform recreation activities‘, were also significant predictors of post-treatment oral cancer patients‘ HRQoL. These findings are not surprising as the majority of patients in the present study were of the younger age group who often prioritised aesthetics and fitness. Moreover, physical disfigurement caused by oral cancer and its treatment sometimes leads to life-long impacts, notably affecting patients‘ appearance. In another study (Molassiotis & Rogers, 2012), ‗appearance‘ was highly reported among female patients and had a significant impact on their psychological well-being. Likewise, in the present study, females, although few in number, also highlighted concerns of ‗appearance'.

This study also suggested that if patients raised more than four concerns, it could indicate to the clinicians that the patients had low HRQoL. As such, the PCI-H&N could be used routinely to monitor patients' overall HRQoL at each follow-up visits, and it could also inform the clinicians on the progress of patients' well-being. Improvement in managing oral cancer survivors can be achieved by continuously monitoring patients' concerns at each follow-up visits to cater to patients' individualised needs (Parry et al., 2011; Rogers, Lowe, & Kanatas, 2016). However, more importantly, as a clinician, it can provide a better understanding of the impact of oral cancer treatment on patients' quality of life (Vartanian et al., 2017).

5.9.3 Association between patient's concerns and patients' psychological distress level.

A previous study had shown that patients' concerns and their psychological distress are inter-related (Krebber et al., 2016), but this association was inconsistent in the present study as the number of concerns was not related to patients' psychological distress. Instead, this study suggested that patients' cancer staging and time since completion of treatment were associated with the risk status of psychological distress level.

In addition to the number of selected concerns, psychological distress was found to be significantly associated with patients' ‗emotional status domain', which was slightly in contrast with a study conducted by Ghazali et al. (2017). In her study, significant distress was strongly associated with (i) physical and functional well-being, and (ii) psychological and emotional well-being domains (Ghazali, Roe, Lowe, Tandon, Jones, Shaw, et al., 2017).

In terms of specific concerns, another study demonstrated that patients at risk of psychological distress had highly related specific concerns on ‗problems with mood‘ (17%) and ‗anxiety‘ (10%) (Kanatas, Ghazali, Lowe, & Rogers, 2012), which in the present study showed lower proportions (problem with mood: 1.2%; anxiety: 5.9%). In contrast, the present study revealed that post-treatment oral cancer patients were more likely to highlight concerns on ‗ability to perform daily activities‘ and ‗feeling depressed‘ whereby patients who were at risk for high distress level were 14.3 times more likely to choose ‗feeling depressed‘. This result implied that Malaysian oral cancer patients were at risk of feeling distressed when they felt restricted from performing their daily activities such as working or house chores, unlike patients in the earlier study who were at risk of psychological distress solely due to their emotions only. It can be postulated that the inability to function as a normal human being does have an impact on our patients especially as they were of younger age groups.

In clinical practice in Malaysia, DT level of four and above suggests that patients were at risk of distress, requiring further referral for psychiatric management (Yong et al., 2012). Because of this, PCI-H&N could be used as an indicator for the clinicians to detect the early signs of significant psychological distress problems with a cut-off point of four items (Ghazali, Roe, Lowe, Tandon, Jones, Shaw, et al., 2017). Although the present study observed a non-significant association between the number of concerns and psychological distress, nevertheless, there were significant associations found between patients‘ emotional domain and specific items (‗ability to perform daily activities‘ and ‗feeling depressed‘). Thus, the potential of PCI-H&N as a screening tool should be explored in the future. Psychological issues among post-treatment oral cancer patients are undoubtedly relevant and typical, which require further psychological support services (Semple, Lannon, Qudairat, McCaughan, & McCormac, 2018).

Guidelines and clinical protocols, such as the National Comprehensive Cancer Network (NCCN) (2019), were developed as standard protocols in managing psychological distress among head and neck cancer patients from the point of diagnoses (Riba et al., 2019). This attention proves that psychological issues among post-treatment oral cancer patients cannot be overemphasised (Semple et al., 2018).

Currently, it is not a routine practice to assess patient‘s psychological distress level by using a questionnaire on psychological health status among oral cancer patients either at diagnosis phase or during routine post-treatment oral cancer follow-up consultation (VanHoose et al., 2015; Yong et al., 2012). Since the findings from this study and other similar studies (Basch et al., 2016; Ghazali, Roe, Lowe, Tandon, Jones, Shaw, et al., 2017) have shown that post-treatment oral cancer patients can have a mental health impacts, therefore, clinicians should anticipate these significant psychological distress problems before initiating oral cancer treatment. The importance of supportive care, for example, reassurance, could be invaluable and may enable patients to cope with the impacts of oral cancer treatment more effectively.

5.9.4 Association between patient’s concerns and patient’ satisfaction with follow-up consultation.

Various barriers exist in establishing good patient-clinician communication, especially during follow-up consultations. These barriers lead to patients‘ unmet needs, under-reporting their concerns, and may also contribute to patients‘ reluctance in sharing their worries (Baile & Aaron, 2005; Ha & Longnecker, 2010; Rogers, Clifford,

& Lowe, 2011; Thorne et al., 2013). Patients‘ satisfaction with the consultation is subject to their expectation of whether their concerns had been addressed (Brown et al., 2009). Nevertheless, this also depends on the health provider‘s ability to respond to patients‘ needs and preferences (van Overveld et al., 2018).

Many patients in the present study were satisfied with their follow-up consultation sessions. Also, patients who were satisfied selected fewer concerns (0-3 items). This outcome could be because most of the clinicians involved in this study were the patients‘ regular clinicians during their routine follow-ups. Thus, both patients and clinicians had already developed a good rapport that was able to meet these patients‘ needs (van Overveld et al., 2018). As such, these could be the possible reasons for the non-significant association between patients‘ satisfaction with the consultation and PCI-H&N domains. In particular, patients were mostly satisfied regarding their discussion on issues that were related to physical status and emotional domains.

5.10 Usefulness and feasibility of PCI-H&N in assessing post-treatment oral cancer concerns: Quantitative feedback from patients and healthcare providers

Patients, clinicians, and dental assistants involved in this study gave feedback regarding the usefulness and feasibility of PCI-H&N use in the routine follow-up consultation. Two versions of PCI-H&N were used in this study, the paper version and computerised web-based version. In Malaysia, the paper version of PCI-H&N was first introduced by Hatta, Doss & Rogers. (2014), whereas in the Western countries, PCI was introduced in the form of computerised web-based either by using touch screen devices or desktops (Ghazali et al., 2015; Rogers et al., 2009). The usefulness and feasibility of PCI-H&N are discussed according to the previously mentioned groups.

5.10.1 Post-treatment oral cancer patients

Patients' feedback on the feasibility of the paper and computerised web-based versions was obtained from the two study groups of PCI-H&N users. There was no significant difference between the two versions. Scott et al. (2013) found similar findings between the paper and touch screen technology PCI used. Another local study detected no significant association between PCI-H&N feasibility and patients' profile (Hatta, Doss & Rogers, 2014). However, patients from both groups showed positive responses in terms of time spent in completing the prompt list, which suggested that PCI-H&N was not time-consuming for patients to fill. These positive findings are much valued as additional time spent in completing the prompt list can be a discouragement for future use as a routine procedure (Kanatas, Mehanna, Lowe, & Rogers, 2009). The present study reported that patients took less time to complete the paper version than the computerised web-based version. Additionally, the time spent for the paper version (4.0 ± 3.7 mins; 3.87,5.87) in the present study was slightly shorter than the study conducted by Hatta et al. (2014) which was nearly 6 minutes (5.9 minutes; 95% CI=5.1-6.7). The time spent in Hatta et al. (2014)'s paper version study was similar with the time spent among those who were using the computerised web-based version of PCI-H&N in the present study.

Most of the patients also agreed that the prompt list helped them to identify the problems they needed to discuss with their clinicians during the consultation, and it also helped them to recall the issues of their concerns. It was observed that three-quarters of the computerised web-based patients reported that the prompt list helped them to remember their concerns, which is consistent with a previous local study (Hatta et al., 2014) and an earlier study by Rogers et al. (2009).

The present study showed a higher proportion of patients might prefer to use the paper version of PCI-H&N in the future compared to the computerised web-based as more than one-quarter of patients from the computerised web-based had difficulties using it. Patients were more confident to use the paper version, especially among IT illiterate patients, as some patients found the keyboard difficult to operate (Caprani, O'Connor, & Gurrin, 2012). This result is not surprising as the majority of post-treatment oral cancer patients are the elderly who are not familiar with IT (information technology) (Caprani et al., 2012).

Besides, the use of any digital form of question prompt list (QPL) is a novelty in healthcare in Malaysia as not all hospitals are fully IT-supported to enable the PCI-H&N computerised web-based version to be used. The situation is unlike other countries where the computerised web-based version is commonplace that they considered the paper version as a substitute (Rogers et al., 2009). Only if patients feel the procedure is not a burden and worthwhile to continue, they would consider using the prompt list again on their subsequent follow-up clinic. Hence, it may ensure sustainability and the possibility of data continuity (Millsopp, Frackleton, Lowe, & Rogers, 2006).

Although PCI-H&N has been used in the UK since 2009 (Rogers et al., 2009), a study showed that about one-third of the participants (n= 31 patients) still preferred to be assisted and complete the prompt list in a separate room compared to the rest who could complete it independently at the waiting area (Rogers & Barber, 2017). Thus, similar finding was observed among patients in the present as they would prefer to be assisted in completing the PCI-H&N and other questionnaires involved. Being assisted could probably make them feel confident, accommodating and faster in completing the questionnaires.

5.10.2 Clinicians

Meanwhile, the consultation time spent by the clinicians was found to be shorter for the computerised web-based than the paper version. A summary sheet that was generated from the computerised web-based version showed only the items that have been selected by the patients. These summarised concerns could probably be one of the reasons that enabled the clinicians to be more focused during the consultation session as it highlighted only the concerns selected by patient, therefore, requiring lesser effort (lesser time spent) to browse through the selected concerns.

All the clinicians involved in this study used the PCI-H&N to browse through their patients‘ concerns to guide the follow-up consultation besides the normal clinical examination. They agreed that the PCI-H&N could establish a more focused consultation session and since the prompt list contains all the possible issues related to patients‘ HRQoL, it helped the patients to recall and actively highlighted their concerns or worries more precisely. Thus, PCI-H&N created more sharing and open communication between them and their patients (Rogers, Ahiaku, & Lowe, 2018; Rogers et al., 2009).

However, a minority of clinicians believed that by using PCI-H&N, it lengthened the consultation session as patients tended to select all the issues that they had experienced and not confined these to the past seven days.

In terms of its usage in routine practice, some clinicians deemed it not practical to be conducted at their facilities due to certain constraints which need to be addressed (this will be further discussed in the next section 5.12).

Most of the clinicians preferred the paper version compared to the computerised web-based version, and this is probably due to the availability of only one touch screen gadget allocated at their clinic compared to the paper version which could be printed and be easily and readily distributed to patients.

5.10.3 Dental surgery assistants (DSA)

Administrating the prompt list to patients was conducted by the dental surgery assistants at the registration counter, and based on the feedback questionnaire among the DSAs, only one DSA reported to face some difficulty in explaining the purpose of PCI-H&N use to patients. According to this DSA, the PCI-H&N disrupted the registration process at the counter which tended to delay patient registration time. This needs to be noted as patient registration time is one of key performance index (KPI) indicators set by Ministry of Health, Malaysia. On the other hand, a previous local study revealed that DSAs perceived the PCI-H&N to prolong the registration process at the counter (Hatta, Doss & Rogers, 2014). As such, there is a need to address those issues to avoid backlog at the patient registration counter area in the future. PCI-H&N did not prolong the registration time as it was issued to patients after they had been registered, but the DSAs still preferred for the patients to complete the prompt list on their appointment day at the clinic rather than at patients‘ home and be brought along on the appointment day. This preference was also in agreement with the finding in a systematic review (Anatchkova et al., 2018). In terms of the preferred mode of PCI-H&N, both versions were accepted by the DSAs.

5.11 Overall discussion summary of quantitative findings in Chapter 5

Dental health and oral function constituted the six most frequent patient concerns with ‗fear of cancer coming back‘ being the topmost concern endorsed by this study cohort. The number of concerns was relatively lower compared to other studies, which implied that our study sample had fewer worries than those in the other studies, or it could be that they were more reserved in sharing their personal concerns with outsiders. The number of concerns selected by patients was significantly associated with ‗time after treatment completed‘ and patients‘ HRQoL. With time, patients learned to adapt and cope with the new changes in their life due to oral cancer and from the side-effects of the treatment received. Nevertheless, a few concerns persisted such as physical status, emotional status and physical functions and it varied between different age groups which perhaps could be related to their individual function and role in the society. The present study revealed few specific concerns that had significant impact on post-treatment oral cancer patients‘ HRQoL and psychological distress.

Overall, the functions and usefulness of PCI-H&N were well accepted and acknowledged by the patients, clinicians, and dental assistants. Most of them preferred the paper version compared to the computerised web-based version due to the digital form limitations, mainly due to IT illiterate patients as many of the patients were the elderly, and insufficient IT infrastructure in the hospitals for the implementation of the computerised web-based version.

5.12 Implementation of PCI-H&N use in OMFS clinics: A qualitative insight from oral health personnel

The aim of a focus group discussion (FGD) was to gain an insight into the PCI-H&N implementation at the study sites, which could be only obtained through a qualitative study. A total of 16 health personnel inclusive of clinicians and dental assistants participated in the FGD session that took place at their OMFS clinics at the end of the data collection period. All those who participated were involved directly in this study and were of various working backgrounds. The feasibility of PCI-H&N from the aspect of its implementation can be evaluated through the health personnel‛s experiences, including their suggestions in sustaining PCI-H&N implementation as a routine procedure during the follow-up consultations. Structured questions were generated based on the ‗FRAME-IT‛ thematic framework to best match the specific objectives (Gonot-Schoupinsky & Garip, 2019).

To date, there are very few studies that have conducted a qualitative study on the feasibility of PCI-H&N. Semple et al. (2018) had conducted a qualitative study to explore the clinicians‛ experiences and perceptions of using PCI on touch screen computers whilst testing the new model of follow-up among post-treatment oral cancer patients attending their follow-up appointments.

5.12.1 Oral health personnel' experiences in the implementation process.

The experience gathered from all the oral health personnel will be discussed under two themes; as their (i) experiences in using PCI-H&N, and their (ii) experiences and barriers faced in the implementation process of PCI-H&N in the OMFS clinics. Eleven domains emerged from the thematic framework for the experiences in using PCI-H&N

and five for the experiences and barriers in the implementation process. These will be discussed in the following sections.

5.12.1.1 Oral health personnel's experiences in using PCI-H&N

a) PCI-H&N paper-version as the preferred version among health personnel

Most of the health personnel preferred the paper version than the computerised web-based version. One of the reasons was that it is easier to be used and managed as most of the study sites are still using a manual patient record system. Thus, the paper version would be easier for record-keeping, which will be enclosed together with patients' records. The limitation of the touch screen device availability restricts its online implementation. During the data collection, a portable Android tablet was provided to each participating site as they do not have such assets. Besides, a paper version seemed to be more acceptable among the elderly compared to the computerised web-based one. A comparative study had shown that the paper version was the most preferred among elderly patients, as most of them were less confident to operate an electronic gadget (Caprani et al., 2012). On the other hand, in Western countries, majority of patients were confident to complete the PCI-H&N using a touch screen gadget independently, and this could maximise resources utilisation (Rogers, Pearson, & Lowe, 2017). Similarly, PROMs or QPL in other studies were mostly administered through an electronic platform which allowed integration with their health clinical record system (Anatchkova et al., 2018). In Malaysia, not all OMFS clinics have been equipped with an electronic patients' record system. Notably, a few studies had shown encouraging findings whereby patients tend to share more concerns especially on sensitive issues such as sexual relationship when using an electronic device and this could potentially provide more accurate information (Cook et al., 1993; Dupont et al., 2009).

b) PCI-H&N is a simple prompt list that can be conducted by dental assistants (DSAs)

The prompt list is a simple inventory, consisting of specific concerns, that was developed for patients to complete independently (Rogers et al., 2009). With two types of languages available, this prompt list was easily explained to the patients by the DSAs at the registration counter.

c) Patient‘s ability to complete PCI-H&N with and without assistance

As observed in the quantitative phase of the present study, it was demonstrated that most patients required assistants in completing the PCI-H&N for both versions with a higher proportion being among the computerised web-based version. Most of post-treatment oral cancer patients in Malaysia are mainly the elderly who requested assistance to complete the PCI-H&N as they were not confident to do it independently (Rogers et al., 2017). In another study, assistants were to assist the elderly on a TST PCI version, especially among those with less IT literacy or with an eyesight problem (Semple et al., 2018). Besides that, as a newly introduced prompt list, it is common for patients or individuals to inquire and request for assistance.

d) PCI-H&N acts as a standard guideline for clinicians during post-treatment follow-up consultation.

The specialist and non-specialist clinicians managed the follow-up consultation clinics. The variation of the communication skills due to their different experiences caused disparity in delivering information during the follow-up consultation sessions (Ezat, Fuad, Hayati, Zafar, & Kiyah, 2014). In the present study, the clinicians found that the prompt list in both versions helped to standardise their consultation sessions by addressing the patients‘ selected concerns which the patients might encounter after they had completed the treatment. By using the prompt list, the clinicians would not miss any aspects that should be discussed during a follow-up session. Besides being a standard guideline for them, this approach could ensure holistic patient-centred care being practised among the clinicians (Rogers et al., 2016).

e) PCI-H&N provides a glance of patients‘ general health state.

The clinicians ‗eyeballed‘ the summary sheet that was attached to patients‘ clinical records before they started the consultation sessions. Hence, the clinicians were able to recognise patients‘ concerns and relate it to patients‘ current well-being specifically concerning HRQoL and psychological distress level (Ghazali, Roe, Lowe, Tandon, Jones, Brown, et al., 2017; Rogers et al., 2009).

With the prompt list, the consultation sessions were more focused as the scope of discussion had been identified based on patients concerns ticked on the PCI-H&N. Being clinicians, however, they were more concerned about the clinical outcomes than the patients‘ HRQoL and psychological distress. The clinicians should be made aware that previous studies had reported the importance of assessing patients‘ HRQoL status and psychological distress to achieve positive clinical outcomes and to increase survivorship (Shunmugasundaram et al., 2019). The clinicians also mentioned that by patients sharing their concerns, they might identify certain personal issues that usually will not be disclosed by their patients.

f) PCI-H&N is able to provide a holistic patients‘ care approach to post-treatment oral cancer patients.

According to the clinicians, patients who used PCI-H&N were satisfied with the clinicians‘ approach during the consultation session as they covered all aspects of the patients‘ concerns. Additionally, patients felt the clinicians had shown more care to them and treated them ‗more humanly‘ rather than just for their clinical assessment.

Providing individualised patients' care, as suggested by WHO (2007) and Carr and Higginson (2001), support a holistic patient-centred care approach as it covers all non-clinical outcomes specifically related to patients‘ HRQoL and psychological distress concerns that can address patients‘ needs, values, and wishes (Epstein, Mauksch, Carroll, & Jaen, 2008).

g) PCI-H&N promotes the multidisciplinary team

PCI-H&N listed all the concerns that patients could select based on their current well-being, to be discussed with their clinicians. Some of the concerns were non-dental related issues, which needed to be further managed by other specialists. As such, PCI-H&N encouraged the clinicians to promote multidisciplinary team management (MDT) among other related specialities in providing holistic patient care (Brady, Goodrich, & Roe, 2020). Among the specialities that are related in managing post-treatment oral cancer patients are ear, nose, and throat (ENT) specialist, speech therapist, nutritionist or dietician, or the psychiatrist. One of the clinicians mentioned that they could address not all the patients' concerns, but those concerns if left untreated, could lead to negative outcomes mainly related to the patients‘ HRQoL and psychological distress. As demonstrated in a study by Ghazali, Roe, Lowe, Tandon, Jones, Shaw, et al. (2017), post-treatment oral cancer patients are at risk of psychological distress, which needs further management by a psychiatrist.

h) PCI-H&N helps patients to identify their concerns.

The clinicians realised that their patients could inquire more on other related concerns than those just confined to the oral cavity and cancer site, especially with regards to their emotional status. Patients were unaware that there were more than just clinical outcomes assessment during the follow-up consultation as non-clinical outcomes are equally important as clinical progress (Basch et al., 2016). Notably, the clinicians agreed that PCI-H&N had made their patients realise about the broader scope and options that are available for them to discuss with their clinicians. The findings of the present study are encouraging as it can postulate future patients being actively involved in the consultation sessions. By using the PCI-H&N, the clinicians believed patients would share more of their concerns with their clinicians.

(i) PCI-H&N encourages empowerment in patients

The traditional concept of clinicians enquiring information from their patients is through close-ended questions (Susan, 2013). However, with the use of this prompt list, the clinicians realised it encourages empowerment among the patients to highlight their concerns and discuss them with their clinicians. As such, the prompt list will act as a guide on the patients' ambivalent issues and enable them to address their concerns.

j) PCI-H&N could be useful for patients‘ self-assessment of their current well-being.

Interestingly, the clinicians found that this prompt list would be able to encourage empowerment and knowledge sharing among post-treatment oral cancer patients. The clinicians noticed that the prompt list could be used as patients‘ self-assessment of whether the patients are having any of the concerns listed. The number and types of concerns selected by the patients could be self-informed to reflect their general health state without being informed by the clinicians during the consultation. This approach could promote patients‘ knowledge of their health status condition (Semple et al., 2018).

k) PCI-H&N provides added value during the patients‘ waiting time

PCI-H&N was not only viewed as a prompt list but also utilised patients‘ waiting time productively. It was valued to enlighten post-treatment oral cancer patients while they were waiting for the consultation session, and this gave them a chance to understand their experiences or impacts of their disease. This finding was also found in a recent study by Semple et al. (2018), whereby the PROs and PCI (in a computerised system) were found to be useful items with productive use of patients‘ waiting time before the consultation session.

5.12.1.2 Oral health personnel’s experiences and barriers faced in the implementation process of PCI-H&N in the OMFS clinics

a) Implementing PCI-H&N among health personnel and patients highly depended on individual acceptance.

Acceptance of any new procedure or intervention would depend on whether it could convince the implementers on the benefit of the new procedure besides providing training. Also, they needed to be clear on the specific job scope involved. With a better understanding of the implementation, it would ensure a smooth process at sites and encourage voluntary participation. Similarly, patients were also willing to participate in this study if they understand the benefit of the study and the procedure involved. The health personal involved should be regularly reinforced from time to time to ensure sustainability and smoothen the implementation process (Trautmann et al., 2016).

b) Administering PCI-H&N requires additional human resource.

The success of implementation would rely on the main factor of human resources to ensure that the intervention is sustainable and do not disrupt the existing work process and increase the burden on the staff (Grimshaw, Eccles, & Tetroe, 2004). In the FGD, two responses were encountered. Some facilities could run the new procedure without needing additional resources as it only required a simple workflow to issue the PCI-H&N to post-treatment oral cancer patients. However, in other facilities, additional resources are required to ensure a more organised and smoother workflow. In a different systematic study, it was suggested that high turnover and staff shortage could result in a burden for the implementation of this new procedure or intervention (Geerligs, Rankin, Shepherd, & Butow, 2018). Furthermore, most of the post-treatment patients in this study preferred to be assisted, which implied an additional workload for the staff.

c) Inadequate supportive infrastructure facilities: IT equipment and interrupted internet connection.

Another barrier of implementing the computerised web-based version is the lack of information technology (IT) infrastructure at the facilities. Issues of unstable internet connection and lack of appropriate equipment such as touch screen computer gadget and printer should be resolved and made readily available. Unstable internet connection disrupted the use of computerised web-based and subsequently prolonged patients‘ time in completing the PCI-H&N. Subsequently, this would probably create tension among the staff who were assisting the patients (Geerligs et al., 2018). Undoubtedly, embedding IT approach in scheduled consultation sessions can improve patient management without wasting limited human resource, and the computerised web-based PCI-H&N version can be integrated with the available health system management used in the facilities (CJ Semple et al., 2018). That is also one of the reasons there is increasing interest in the use of IT approach in obtaining comprehensive PROs among oral cancer patients (Rogers et al., 2018; Scott et al., 2013).

d) PCI-H&N was available in two languages only (Malay and English).

Another barrier in Malaysia is its multi-language ethnic composition. Often, many validated PROMs or QPL were prepared in multi-languages. This accommodation is to facilitate participants who have difficulty in understanding Malay or English languages, mainly from Sabah and Sarawak that comprise multi-ethnic population, among the elderly as well as patients of lower educational background. Hence, to avoid misinterpretation of translation by researchers at sites, the multi-language PCI-H&N questionnaire would be needed for future use to ensure high-quality data. Further development of multi-language questionnaires would seem to be necessary and require a more sophisticated process and not just forward-back translation (Fujishiro et al., 2010).

e) PCI-H&N may prolong follow-up consultation time.

The clinicians believed that conducting the consultation using PCI-H&N would prolong the consultation duration, a limitation on a busy clinic day. Although the prompt list helps to identify specific concerns for a more targeted and focused discussion, however, some patients tend to select more of irrelevant issues for discussion without prioritising them. If all the selected items were to be discussed during the consultation session, it might prolong the consultation session and cause longer waiting time for other patients who are waiting to be seen. Some OMFS clinics could not afford to allocate a specific day for longer consultation time as the clinicians had other clinical duties that need to be fulfilled.

Therefore, the follow-ups for post-treatment oral cancer patients are integrated with other clinics‘ appointments. In contrast, previous studies reported that the consultation time was not prolonged by using the PCI (Hatta, Doss & Rogers, 2014;

Rogers et al., 2009; Scott et al., 2013). This finding was also in agreement with another qualitative study which reported that the use of PCI and supplementary QOL questionnaire did not lengthen the consultation time as it creates a more focused consultation on patients‘ selected concerns (Semple et al., 2018).

5.12.2 Suggestions for improvement of PCI-H&N implementation.

There has been an increasing interest in optimising the use of PROs for health patient management during routine cancer patients‘ follow-ups. Many studies had shown positive evidence of using it (Ghazali, Lowe, & Rogers, 2012; Hatta, Doss & Rogers, 2014; N. Miller & Rogers, 2018; Rogers et al., 2019). This favourable evidence has shown the potential value of its function among post-treatment oral cancer patients, chiefly when integrated into routine care during patients‘ follow-ups (Warrington, Absolom, & Velikova, 2015). During the FGD sessions, the health personnel had come up with few suggestions for improvement as mentioned below.

i) The option of PCI-H&N to be completed in the surgery room or at home

Typically, PROs or QPL were conducted before patients were called into the surgery room for their consultation, requiring them to complete the form at the waiting area or in a private room. This FGD suggested completing the prompt list when the patient is called into the surgery room before the start of consultation with the clinicians. This suggestion seemed to be more feasible to lessen the burden of counter staff, and to avoid wrongly giving the PCI-H&N to patients other than oral cancer patients. It can also allow patients to fill up the prompt list in the comfort and privacy of the consultation room.

There were suggestions for the prompt list to be completed at home before they attended the follow-up appointment. However, the shortcomings of this approach would be that patients may leave it at home, and this can only occur with the paper version. As demonstrated in a study by Bolman, Brug, Bär, Martinali, and van den Borne (2005), whereby a QPL sent to patients to be completed at home prior the follow-up appointments showed low usage rate as patients did not bring the QPL on the follow-up day. A computerised web-based version is possible to do so, by creating specific access for the patients to complete the prompt list section only at home. The currently used computerised web-based version does not have this patient‘s access. A previous study assessing cancer patients‘ psychological distress level reported a higher percentage of patients who decided to complete the DT questionnaire (computerised web-based) at home (90.1%) rather than at the clinic during their appointments (Wagner et al., 2015).

ii. Prioritising patient’s concerns by a scoring system

In a busy clinic day, time is always a barrier, and only limited time can be spent on each patient. As such, providing a scoring system in the prompt list could guide the clinicians to prioritise their patients‘ concerns and discuss the most critical issues. By doing so, patients‘ most pressing unmet needs can be addressed within the limited time without causing a delay to other patients‘ appointment time.

5.13 Overall Summary of FGD findings in Chapter 5

The FGD sessions among the health personnel had revealed the insights of PCI-H&N feasibility, specifically on its implementation as a routine procedure during post-treatment oral cancer follow-ups. The positive experience gained from the health personnel has shown the significant functions of the prompt list in addressing patients' unmet needs and guiding the clinicians for a standardised and a more quality consultation. The limitations and barriers faced at individual facilities need to be investigated for future implementation. A few suggestions have been listed out to ensure the sustainability and smooth workflow of its implementation.

CHAPTER 6: CONCLUSIONS AND RECOMMENDATIONS

6.1 Conclusions

The conclusions from this study are based on the study objectives and listed in the following sections. A total of 123 post-treatment oral cancer patients had been recruited in the present study of which 55 patients for PCI-H&N paper version, 30 patients for the computerised web-based version and 38 patients underwent conventional follow-up consultations.

i) **Objective 1: To identify post-treatment oral cancer patient concerns by using PCI-H&N (paper version & computerised web-based version) during follow-up consultation in terms of:**

   a. types of concerns selected.

   b. number of the concerns selected

a) **Types of concerns selected**

- The physical status domain was highly selected among post-treatment oral cancer patients, followed by emotional status.
- The three most specific concerns most selected by the patients in descending order were ‗recurrence or fear of cancer coming back‘, issues of their ‗dental problems‘, and ‗chewing‘.
- Patients who used the computerised web-based version showed a significant higher number of concerns namely ‗taste‘, ‗dry mouth‘ and ‗coping‘ whereas ‗coughing‘ was significantly higher among those who used the paper version. However, these significant difference have little impact on clinical practice as it reflects the different patients‘ groups who used the PCI-H&N.

b) <u>Number of concerns selected</u>

- Ranging from 0-17 concerns, the median number of the patients‘ concerns selected was three (IQR: 1-5.5).
- Slightly more than two-fifths of patients selected four or more concerns, one-third selected one to three items whereas almost one-quarter did not select any concerns.

ii. Objective 2: To assess short term impact of PCI-H&N use and non-use on health- related quality of life and psychological distress levels among post-treatment oral cancer patients.

Two primary outcomes were assessed for short term (1-month duration) impact among patients who used the PCI-H&N (paper or computerised web-based version) and among those who had conventional follow-up consultations (non-PCI-H&N use).

a. Patient‘s HRQoL

- Within the PCI-H&N user group, a significant improvement was observed in total MAQ score after one month which comprised issues related to spiritual aspects, mouth opening, shoulder movement, body numbness, appetite, mouth ulcers and food stagnation.
- Between the PCI-H&N and non-user PCI-H&N group, there was no statistically significant difference observed in all HRQoL domains after one month. However, a slight non-significant improvement in MAQ score was observed from baseline to 1-month among those who used the PCI-H&N.

b. Patient‘s psychological distress

- There was no significant difference observed in psychological distress levels within the PCI-H&N groups, or between PCI-H&N and non-PCI-H&N user groups from baseline to 1 month time-point. All groups (PCI-H&N and non-PCI-H&N users) showed lower DT level (DT<3) at baseline and at 1-month time point.
- After one month, a significant lesser number of patients among the PCI-H&N groups reported lesser number of specific problems listed in the DT questionnaire from the baseline which include ‗fatigue', ‗tingling at hands and feet', and ‗financial/ insurance' problems.

iii. Objective 3: To compare patient satisfaction with follow-up consultation among PCI-H&N users (paper version and computerised web-based version) and non-PCI-H&N users (control).

- Patients' satisfaction with the consultation showed no significant difference between patients who used PCI-H&N and those in conventional consultation sessions. All the patients in the present study suggested a high satisfaction with the clinicians.

iv. Objective 4: To investigate association of PCI-H&N domains and specific concerns among post-treatment oral cancer patients (in terms of number and types of concerns selected) with patients’ details.

Number and type of patients‘ concerns could significantly discriminate in terms of:

a) Patients’ Cancer Characteristics.

Number

- Number of patient concerns was only able to discriminate patients‘ cancer characteristics in terms of _time after treatment completed‘ (p<0.001).
- Majority of the _one-month until one-year‘ post-treatment patients had a high number of concerns which suggested that a high number of concerns was associated among those at the earlier phase of post-treatment/ recovering.

Types

- _Time after treatment completed‘ was significantly related to physical status, personal functions, and treatment-related domains. These domains were significant among the _1-month until less than 1-year‘ post-treatment patient group.
- Specific concerns selected namely _chewing/eating‘, _mouth opening‘, _swelling‘, _weight‘, _ability to perform daily routines‘, _cancer treatment‘ and _health supplement/diet-related issues‘ were highly significant among those patients in the early phase of recovering (_one month until less than one year post-treatment‘).

b) Patients’ Health- Related Quality of Life.

Number

- Patients‘ HRQoL was associated with number of concerns selected. Patients with lower HRQoL scores (range: 77- 140) had more numbers of concerns (4-17 items).

- In terms of HRQoL quartiles, high number of patients‘ concerns with a median of five patient‘s concerns (IQR: 3-7) were reported among those with a median HRQoL score of 113 (IQR: 91-125).

Types

- In terms of PCI-H&N domains, personal functions domain strongly predicted patients‘ HRQoL whereby more concerns selected by patients in the personal functions domain predicted lower HRQoL.
- Patients‘ HRQoL can be moderately predicted by PCI-H&N specific concerns. ‗Appearance‘ and ‗ability to perform recreation activities‘, with ‗chewing and eating‘ was a stronger predictor for lower HRQoL score.

c) Patients’ Psychological Distress Level.

Number

- No significant difference was observed between the number of concerns selected and patients‘ psychological distress.

Types

- Patients‘ emotional status was the only domain in the PCI-H&N that predicted patients‘ psychological distress level.
- Post-treatment oral cancer patients were 24 times more likely to have higher psychological distress (DT ≥ 4) if they select concerns in the emotional domains.
- In terms of specific concerns, patients who selected ‗ability to perform recreational activities‘ and ‗feeling depressed/sad‘ were seven times and 14

times more likely (respectively) to have higher psychological distress level (DT ≥4) than patients who selected other PCI-H&N items.

Number and type of patients‘ concerns were not able to significantly discriminate in terms of:

a) **Patients's sociodemographic background**

b) **Patients' satisfaction with follow-up consultation**

- No significant difference was observed between the number and types of concerns selected and patients‘ sociodemographic background and their satisfaction with follow-up consultation.
- All patients were satisfied with the follow-up consultation.

v. Objective 5: To assess the usefulness and feasibility of PCI-H&N during the follow-up consultation in terms of:

Quantitative data

a) **patients', clinicians' and DSAs' feedback.**

b) **time taken by the patients to complete the prompt list prior consultation session.**

As for sub-objective ‗a‘ and ‗b‘, the usefulness and feasibility of PCI-H&N was assessed from patients, clinicians and DSAs feedback as follows:

a) Patients

Usefulness

- From patient's perspectives, both versions of PCI-H&N showed no significant difference in terms of its usefulness in helping them in identifying their concerns during consultations.
- Nevertheless, the paper version showed higher non-significant proportion in relation to recalling issues that they wished to discussed with their clinicians, and their intentions to use PCI-H&N in future visits.

Feasibility

- In terms of its feasibility, a non-significant higher proportion of patients who used the computerised web-based PCI-H&N agreed that the prompt list did not take a long time. However, patients were more comfortable and confident in completing the prompt list in the paper version.
- PCI-H&N in the paper version took a significant shorter time (4.0 mins) to be completed by patients compared to the computerised web-based version (6.0 mins).

b) Clinicians

Usefulness

- Noteworthy, all of the clinicians referred to the prompt list prior the consultation, agreed to use it in the future and that the prompt list

    i) helped in a focused consultation targeting at patients' concerns,

    ii) helped their patients to identify issues that they wanted to discuss with their clinicians,

    iii) was a quick glimpse of patients' concerns,

iv) moderately practical to be use in the routine follow-up consultation,

v) adequately able to address patient‘s concerns during the consultation session.

Feasibility

ii) Almost three-quarters of the clinicians perceived that the prompt list prolonged the consultation session.

iii) Paper version was the most preferred PCI-H&N version compared to the computerised web-based version.

c) DSAs

Feasibility

- Generally, the feedback were positive. All agreed PCI-H&N did not prolong registration time and majority agreed they did not have difficulties in explaining to patients, it did not disrupt the registration process and preferred patients to complete the prompt list on their appointment day rather than at home.
- Almost two-thirds chose paper-version compared to computerised web-based PCI-H&N version.

Qualitative (FGD) information

c) Oral health personnel’s experiences in the implementation process.

d) Suggestions for improvement for PCI-H&N implementation.

The findings from sub-objective ‗c‘ and ‗d‘ were obtained from FGD sessions among healthcare personnel. The experiences gained from using the PCI-H&N and suggestions from the health personnel as listed below:

c) Oral health personnel’s experiences in the implementation process

1. Oral health personnel experiences in using PCI-H&N
    - PCI-H&N paper-version is the preferred version among health personnel
    - PCI-H&N is a simple prompt list that can be conducted by dental assistants (DSAs)
    - Patient‘s ability to complete PCI-H&N with and without assistance. Most who needed assistance were among the elderly and with less IT literacy.
    - PCI-H&N acts as a standard guideline for clinicians during post-treatment follow-up consultation to ensure a standard practice among the clinicians with various clinical background and to avoid disparity in conducting follow-up consultations.
    - PCI-H&N provides a glance of patients‘ general health state. The clinicians ‗eyeballed‘ the summary sheet and were able to recognize patients concerns. As such, a more focused consultation session can be conducted.
    - PCI-H&N is able to provide a holistic patients‘ care approach to post-treatment oral cancer patients as it covered all aspects of patients‘ concerns.
    - PCI-H&N promotes the multidisciplinary team in providing holistic patient-centred care. There are non-dental related issues raised by the patients which need further management by other related specialities.

- PCI-H&N helps patients to identify their concerns to share with their clinicians to be discussed with their clinicians during consultation session.
- PCI-H&N encourages patient empowerment in addressing their concerns and actively participate in the consultation.
- The clinicians noticed that PCI-H&N could also be useful to the post-treatment patients as a patients‘ self- assessment of their current well-being.
- Filling in the PCI-H&N provides added value during the patients‘ waiting time as it can utilise patients‘ waiting time productively.

2. Oral health personnel‘s experiences and barriers faced in the implementation process of PCI-H&N in the OMFS clinics:
    - Implementing PCI-H&N among health personnel and patients highly depended on individual acceptance.
    - Administrating PCI-H&N requires additional human resource as most OMFS facilities have inadequate assistants to clinicians‘ ratio and implementing PCI-H&N may increase their work load.
    - Inadequate supportive infrastructure facilities: IT equipment and interrupted internet connection. Not all facilities were well equipped for the computerised web-based version.
    - PCI-H&N was available in two languages only (Malays and English)
    - PCI-H&N may prolong follow-up consultation time as patients sometimes tend to select more irrelevant issues without prioritising them.

d) **Suggestions for improvement of PCI-H&N implementation**.

- The option of PCI-H&N to be completed in the surgery room or at home prior to patients‘ appointments.
- Prioritising patient‘s concerns by a scoring system

6.2 Recommendations

The following recommendations are made based on the study findings:

1. This study revealed that PCI-H&N encouraged patients to share their concerns which they may not have highlighted before. Highly selected concerns were about physical status, personal function and emotional domains. With regards to patients‘ concerns, these recommendations are proposed:
   a. To integrate early discussions between clinicians and their patients on psychological issues (e.g. distress, anxiety and fear of recurrence) at the diagnoses phase. This is in anticipation of emotional impact at post-treatment phase and assist in their coping ability. The availability of National Comprehensive Cancer Network (NCCN, 2011) protocol in managing distress among head and neck cancer patients can be use a guideline in managing our patients.
   b. To involve other dental specialities such as the prosthetics and oral medicine specialists as part of MDT combined clinic especially in managing related to dental issues e.g. swallowing, eating and dry mouth. These dental issues were among the most selected by post-treatment oral cancer patients.
   c. In a situation where time for the consultation session is restricted, patients may prioritise their selected concerns by choosing the most pressing concerns that they wanted to discuss with the clinicians. However, if time permits, all the concerns selected can be discussed with their clinicians.

2. Encourage the clinicians at OMFS clinics throughout Malaysia to use PCI-H&N during their follow-up consultation sessions for continuous monitoring of patients‘ post-treatment outcomes especially patients HRQoL and psychological distress levels. The continuous use of PCI-H&N could improve the knowledge gap in

research pertaining to these patients‘ outcomes. This monitoring could assist the clinicians in planning for future treatment management.

3. This prompt list can be used to accommodate patients‘ preference, as described below:
    a. can be given to patients to be completed prior to the appointment day
    b. can also be used in tele-consultation for selected patients according to clinicians‘ discretion.

4. With regards to the usefulness and feasibility of PCI-H&N:
    - Paper version is recommended for the current use until the IT supported facilities and assets (e.g. touch screen tablet and printer) are equipped in all facilities. However, the computerised web-based version can also be used in those facilities that are already complete with IT facilities. PCI-H&N should be made accessible to patients in hard copy or via web-based sources.
    - PCI-H&N should be made available in multi-languages besides Malay and English to increase acceptance among the patients and ease the health personnel in interpreting the PCI-H&N to their patients.
    - Awareness needs to be created among clinicians and supporting staff on the benefit of integrating the PCI-H&N in follow-up consultation sessions.
    - One model OMFS clinic can be identified among the oral cancer referral centres to facilitate other OMFS clinics to emulate its implementation.
    - Awareness and acceptability of PCI-H&N is needed among our oral cancer patients on the importance of its continuous use in routine follow-up consultation sessions in order to enhance patient care.

5. Future research
    a. Further research can be conducted on the most frequently selected concerns found in this study; ‗recurrence/ fear of cancer coming back‘. A qualitative study could be conducted through the individual in-depth interview to explore patients‘ fear of recurrence cancer that could vary between patient‘s profiles which could assist the clinicians in better patient management. This could also facilitate future psychological distress assessment among oral cancer patients as part of routine patient care commencing from oral cancer diagnosis phase.
    b. Top five most frequently selected concerns among our population were all on dental-related issues that showed a dental MDT approach is much relevant and should be integrated into early oral cancer patient management at diagnosis phase. The importance and effectiveness of the dental management team such as a combined MDT clinic can be assessed through a comparative study at the tertiary centre of oral cancer management at multiple OMFS clinics. Besides that, the effectiveness could be further evaluated through patients‘ outcomes of patient satisfaction and HRQoL.
    c. To involve a wider scope of study sites of the institutional hospital-based OMFS as these centres are also the referral centres for oral cancer in Malaysia. This extended scope could provide additional information on patient-centred care management for oral cancer patients.

    d. Future studies should employ a longitudinal study design to investigate the changes in patients‘ post-treatment outcomes with the use of PCI-H&N. The present study only managed to assess patients‘ outcomes up to 1-month post-treatment. By conducting a longitudinal study of a longer duration, it could determine whether integrating PCI-H&N into the routine follow-up consultations increases patients‘ knowledge on the post-treatment impact, empower them on shared-decision making and improve post-treatment oral cancer patient management.

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LIST OF PUBLICATIONS AND PAPERS PRESENTED.

1. Oral presentation at the 1st Malaysian Association for Cancer Research (MACR) Scientific Conference (3rd) December 2019 at MAHSA University, Selangor, Malaysia. Refer Appendix S and T.
2. Virtual poster presentation at the ICOM 2020 in conjunction with 13th Postgraduate e-conference 8th-9th September 2020. Refer Appendix U