

**THE EFFECTS OF RELAXATION THERAPY
AMONG HEAD AND NECK CANCER PATIENTS
ON QUALITY OF LIFE**

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**DISSERTATION SUBMITTED IN PARTIAL FULFILLMENT
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ABSTRAK

Objektif

Barah kepala dan leher (HNC) menyebabkan kebimbangan dikalangan pesakit kerana kesan daripada penyakit dan juga akibat rawatannya terhadap fungsi kehidupan seharian iaitu pernafasan, pertuturan dan kebolehan untuk menelan. Oleh itu, HNC boleh membawa kesan buruk terhadap kualiti hidup (QoL) pesakit. Tujuan kajian ini adalah untuk mengkaji kesan terapi relaksasi di kalangan pesakit HNC terhadap QoL. Secara khususnya, ianya bertujuan untuk mengkaji kesan perubahan terhadap keresahan (*anxiety*), kemurungan (*depression*) dan QoL dikalangan pesakit HNC yang menjalani terapi relaksasi dan juga pesakit HNC yang menjalani psiko-pendidikan. Kajian ini juga akan menilai perbezaan skor di dalam keresahan, kemurungan dan QoL antara kumpulan terapi relaksasi dan kumpulan terapi psiko-pendidikan sebelum dan selepas terapi dijalankan.

Kaedah

Kajian klinikal dilaksanakan di kalangan pesakit barah kepala dan leher yang telah direkrut secara rawak dari klinik Otorhinolaringologi (ORL) dan klinik Onkologi. Mereka dibahagikan kepada kumpulan kajian dan kumpulan kawalan. Kumpulan kajian menerima terapi relaksasi secara berkala pada minggu 1,2,4 dan 6 di Pusat Rehabilitasi Psikologi @ MENTARI USM, manakala kumpulan kawalan diberikan psiko-pendidikan pada minggu 1 dan 6. Penilaian dilakukan pada minggu 1 (sebelum bermulanya terapi) dan minggu ke-6 (setelah selesai terapi) menggunakan soal selidik Fungsi Penilaian Terapi Kanser-Kepala & Leher (FACT-H&N versi 4) untuk penilaian QoL, dan Skala Keresahan dan Depresi Hospital (HADS) untuk penilaian keresahan dan kemurungan.

Keputusan

Seramai 26 peserta direkrut untuk kajian ini. Terdapat penurunan yang signifikan secara statistik (nilai $p = 0.041$) pada tahap kemurungan selepas terapi relaksasi pada jangka masa 6 minggu. Subskala SWB dan EWB menunjukkan peningkatan dalam skor setelah terapi relaksasi, tetapi tidak signifikan secara statistik (nilai $p > 0,050$). Tidak ada penurunan yang signifikan secara statistik pada tahap keresahan dan peningkatan keseluruhan QoL setelah terapi relaksasi pada tempoh 6 minggu.

Kesimpulan

Sebagai kesimpulan, kajian menunjukkan bahawa terapi relaksasi menunjukkan penurunan tahap kemurungan yang signifikan secara statistik. Ia menunjuk hasil yang baik di kalangan pesakit HNC dalam menguruskan tekanan psikologi yang berpotensi menyumbang kepada QoL yang lebih baik. Oleh itu, terapi relaksasi dapat ditekankan sebagai terapi tambahan sebagai pendekatan holistik dalam pengurusan pesakit HNC.

Kata Kunci: kualiti hidup, kanser kepala dan leher, terapi relaksasi, psikososial

ABSTRACT

Objectives

Head and neck cancer (HNC) is a debilitating condition due to the impact of the cancer and its treatment consequences on the daily basic-life function namely breathing, speech and swallowing. Hence, HNC has been detrimental to the patients, leading to an adverse impact on their quality of life (QoL). The objective of our study was to study the effect of relaxation therapy among head and neck cancer patients on QoL. Specifically, the study aimed to determine changes in anxiety, depression and quality of life score within relaxation therapy and psychoeducation therapy group. It also compared differences in anxiety, depression and quality of life score between relaxation therapy and psychoeducation group at pre- and post-intervention.

Methods

A randomized clinical trial was conducted. HNC patients were recruited from Otorhinolaryngology (ORL) clinic and Oncology clinic. They were randomly grouped into study and control groups. The study group received periodically-time-specific relaxation therapy at week 1,2,4 and 6 at Psychiatric Rehabilitation Center @Mentari USM, whereas the control group were provided with psychoeducation at week 1 and 6. The evaluations were done at week 1 (before commencement of therapy) and week 6 (after completion of intervention) using Functional Assessment Cancer Therapy-Head & Neck (FACT-H&N version 4) questionnaires for assessment of QoL, and Hospital Anxiety and Depression Scale (HADS) for screening of anxiety and depression.

Results

A total of 26 participants were recruited for this study. There was statistically significant reduction ($p\text{-value}=0.041$) in the level of depression after relaxation therapy at 6-week period. The subscale of SWB and EWB showed improvement in scoring after the relaxation therapy, but not statistically significant ($p\text{-value}>0.050$). There was no statistically significant reduction in the level of anxiety and overall improvement of the QoL after relaxation therapy at 6-week period.

Conclusions

In conclusion, the study suggests that the relaxation therapy showed statistically significant reduction in depression level and have a beneficial outcome among HNC patients in managing the psychological distress that later potentially contribute to better QoL. Therefore, the relaxation therapy can be emphasized as an adjunct therapy as part of holistic approach among HNC patients' management.

Key Words: quality of life, head and neck cancer, relaxation therapy, psychosocial

Chapter 1

INTRODUCTION

1.1 INTRODUCTION

The annual incidence of head and neck cancers (HNC) worldwide is more than half a million which is greater in men compared to women¹ and is increasingly seen in younger age group². HNC consists of heterogeneous groups of tumours arising in the oral cavity, nasal cavity, pharynx, larynx, paranasal sinuses, salivary glands, thyroid gland and soft tissue tumour at head and neck region with a multitude of histology. The vast majority of head and neck malignancies are squamous cell carcinomas and characterized by the tendency to recur loco regionally³. It represents the seventh leading most common cancer by worldwide and the frequently associated risk factors are smoking, alcohol consumption, human papillomavirus (HPV) infection (especially for oropharyngeal cancers), and Epstein-Barr virus (EBV) infection (especially for nasopharyngeal cancers in Asia)⁴.

The main treatment modalities of HNC are surgery and radiation therapy with or without chemotherapy aiming for possible curative or palliative intent and is largely depending on the tumour stage and site, expertise available and patient factors. Radiation therapy for local control of HNC comes with undesirable effect including mucositis, skin reaction, pain, risk of osteoradionecrosis, fibrosis, hearing loss and xerostomia⁵.

The survival rate showed slight improvement over the past decade from approximately 50% to 60% with the advancement in treatment modality⁶. Hence, improved survival rate in HNC, in addition with increasing incidence of HNC in younger age group, leads the current management not aiming to increase the chances of cure but also to improve quality of life and psychosocial aspect of the patients.

Patients with HNC may suffer functional impairment that are related to speech, breathing and swallowing as well as disfigurement and dysfunction either due to direct tumour infiltration or as a result of debilitating treatment sequelae^{7,8}. These functional losses lead to significant heightened rates of psychological distress that has negative impact on the

psychological, QoL, and medical outcomes⁹. HNC patients demonstrate significant elevated level in both anxiety and depressive symptoms which vary throughout disease trajectory. High anxiety level is commonly seen at the time of diagnosis due to distractibility, symptoms of overwhelming information and poor sleep¹⁰. The depressive symptom is occurring more as the disease progress when patients have to endure functional deficit in daily life activity particularly dysfunction in salivation, problems with eating, and problems with social contacts⁹. A significant psychosocial distress with different changes in anxiety and depression throughout the continuum of treatment was negatively correlated with QoL^{11,12}. Thus, different method of psychosocial intervention has been addressed to manage the anxiety and depression which eventually improved their QoL.

The quality of life in cancer patient covers a wide range of health related life issues concerning the mental, physical, role and social functioning at the optimum level as well as perception of health, fitness, life satisfaction and well-being¹³. There are many quality of life assessment tools that have been validated and used. Among the commonly used and best validated tools include the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ C30)¹⁴, Functional Assessment of Cancer Therapy-Head and Neck Subscale¹⁵ and University of Washington Head and Neck Cancer Questionnaire¹⁶. Hospital Anxiety and Depression Scale (HADS)¹⁷ and Brief Symptom Inventory-18 (BSI-18)¹⁸ are among frequently used self-report measures of psychosocial distress that are useful for screening for anxiety and depressive symptoms.

Psychosocial therapy is relevant among HNC population due to significant level of distress associated with diagnosis and treatment of cancer. Psychosocial intervention includes cognitive behavioural therapy¹⁹, problem-focused intervention²⁰, coping technique²¹, psychosocial support group²² and psychoeducation²³ have shown variable outcome in alleviation of distress and improvement in QoL.

Relaxation therapy including deep breathing exercise and PMR is a technique to elicit a relaxation response. Deep breathing exercise train the mind to become aware of own breathing sensation thus anchoring focus on the present moment. Progressive muscle relaxation is a mind-body interventions technique consisting of systematic contraction and subsequent relaxation of various muscle group sequentially that attract individual's attention to the skeletal muscle thereby relaxing the whole body. Relaxation response is achieved as the muscle relax with predominant parasympathetic activity that result in reduced heart rate, lowered blood pressure and decreased rate of breathing and improved in mood ^{24,25}.

Many studies on relaxation therapy as a psychosocial intervention have shown variable outcome in other type of cancer population. A study by Isa et al²⁶ on the impact of 6-month applied progressive deep muscle relaxation training among 155 patients with prostate cancer showed statistically significant improvement in anxiety level at end of intervention. In the study also, there was no improvement was observed in depression level at 6-month period. Zehra et al²⁷ studied the effect of 12-week PMR to 31 patients with early breast cancer showed there was no statistically improvement of QoL. However, the study showed there was significant improvement on fatigue and coping styles. A systemic review on PMR as a supportive intervention for cancer patients undergoing chemotherapy indicated that PMR might have a few benefits for these population by improvement in the comfort and reduction of the anxiety level and side effects of chemotherapy²⁸. Yet, the author recognized the shortcomings of the result as there was a small numbers of studies that had poor quality, thus limit the significance of the review. Bravo et al ²⁹, conducted a study on the impact of muscle relaxation techniques on the QoL among heterogeneous groups of 272 cancer patients, revealed that those with symptoms of anxiety showed improvement in the QoL, as measured by the FACT-G.

To date, there are many psychosocial interventions have been performed among HNC patients in order to improve quality of life. Among these, the relaxation therapy among HNC

patients is yet to be treasured. The objective of this study is to study the effect of relaxation therapy among HNC patients on anxiety, depression and QoL. The result of study may add a valuable benefit for better HNC management outcomes.

Chapter 2

OBJECTIVES OF THE STUDY

2.0 OBJECTIVES

2.1 General:

To study the effect of relaxation therapy among head and neck cancer patients on quality of life (QoL)

2.2 Specific:

- 2.2.1 To determine changes in anxiety, depression and quality of life score within relaxation therapy and psychoeducation therapy group.
- 2.2.2 To compare differences in anxiety, depression and quality of life score between relaxation therapy and psychoeducation group at pre- and post-intervention.

Chapter 3

MANUSCRIPT

3.1 Title Page

The Effects of Relaxation Therapy Among Head and Neck Cancer Patients on Quality of Life

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3.2 ABSTRACT

Objectives

Head and neck cancer (HNC) is a debilitating condition due to the impact of the cancer and its treatment consequences on the daily basic-life function namely breathing, speech and swallowing. Hence, HNC has been detrimental to the patients, leading to an adverse impact on their quality of life (QoL). The objective of our study was to study the effect of relaxation therapy among head and neck cancer patients on QoL. Specifically, the study aimed to determine changes in anxiety, depression and quality of life score within relaxation therapy and psychoeducation therapy group. It also compared differences in anxiety, depression and quality of life score between relaxation therapy and psychoeducation group at pre- and post-intervention.

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Conclusions

In conclusion, the study suggests that the relaxation therapy showed statistically significant reduction in depression level and have a beneficial outcome among HNC patients in managing the psychological distress that later potentially contribute to better QoL. Therefore, the relaxation therapy can be emphasized as an adjunct therapy as part of holistic approach among HNC patients' management.

Key Words: quality of life, head and neck cancer, relaxation therapy, psychosocial

3.3 INTRODUCTION

The annual incidence of head and neck cancers (HNC) worldwide is more than half a million which is greater in men compared to women¹ and is increasingly seen in younger age group². HNC consists of heterogeneous groups of tumours arising in the oral cavity, nasal cavity, pharynx, larynx, paranasal sinuses, salivary glands, thyroid gland and soft tissue tumour at head and neck region with a multitude of histology. The vast majority of head and neck malignancies are squamous cell carcinomas and characterized by the tendency to recur loco regionally³. It represents the seventh leading most common cancer by worldwide and the frequently associated risk factors are smoking, alcohol consumption, human papillomavirus (HPV) infection (especially for oropharyngeal cancers), and Epstein-Barr virus (EBV) infection (especially for nasopharyngeal cancers in Asia)⁴.

The main treatment modalities of HNC are surgery and radiation therapy with or without chemotherapy aiming for possible curative or palliative intent and is largely depending on the tumour stage and site, expertise available and patient factors. Radiation therapy for local control of HNC comes with undesirable effect including mucositis, skin reaction, pain, risk of osteoradionecrosis, fibrosis, hearing loss and xerostomia⁵.

The survival rate showed slight improvement over the past decade from approximately 50% to 60% with the advancement in treatment modality⁶. Hence, improved survival rate in HNC, in addition with increasing incidence of HNC in younger age group, leads the current management not aiming to increase the chances of cure but also to improve quality of life and psychosocial aspect of the patients.

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psychological, QoL, and medical outcomes⁹. HNC patients demonstrate significant elevated level in both anxiety and depressive symptoms which vary throughout disease trajectory. High anxiety level is commonly seen at the time of diagnosis due to distractibility, symptoms of overwhelming information and poor sleep¹⁰. The depressive symptom is occurring more as the disease progress when patients have to endure functional deficit in daily life activity particularly dysfunction in salivation, problems with eating, and problems with social contacts⁹. A significant psychosocial distress with different changes in anxiety and depression throughout the continuum of treatment was negatively correlated with QoL^{11,12}. Thus, different method of psychosocial intervention has been addressed to manage the anxiety and depression which eventually improved their QoL.

The quality of life in cancer patient covers a wide range of health related life issues concerning the mental, physical, role and social functioning at the optimum level as well as perception of health, fitness, life satisfaction and well-being¹³. There are many quality of life assessment tools that have been validated and used. Among the commonly used and best validated tools include the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ C30)¹⁴, Functional Assessment of Cancer Therapy-Head and Neck Subscale¹⁵ and University of Washington Head and Neck Cancer Questionnaire¹⁶. Hospital Anxiety and Depression Scale (HADS)¹⁷ and Brief Symptom Inventory-18 (BSI-18)¹⁸ are among frequently used self-report measures of psychosocial distress that are useful for screening for anxiety and depressive symptoms.

Psychosocial therapy is relevant among HNC population due to significant level of distress associated with diagnosis and treatment of cancer. Psychosocial intervention includes cognitive behavioural therapy¹⁹, problem-focused intervention²⁰, coping technique²¹, psychosocial support group²² and psychoeducation²³ have shown variable outcome in alleviation of distress and improvement in QoL.

Relaxation therapy including deep breathing exercise and PMR is a technique to elicit a relaxation response. Deep breathing exercise train the mind to become aware of own breathing sensation thus anchoring focus on the present moment. Progressive muscle relaxation is a mind-body interventions technique consisting of systematic contraction and subsequent relaxation of various muscle group sequentially that attract individual's attention to the skeletal muscle thereby relaxing the whole body. Relaxation response is achieved as the muscle relax with predominant parasympathetic activity that result in reduced heart rate, lowered blood pressure and decreased rate of breathing and improved in mood ^{24,25}.

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To date, there are many psychosocial interventions have been performed among HNC patients in order to improve quality of life. Among these, the relaxation therapy among HNC

patients is yet to be treasured. The objective of this study is to study the effect of relaxation therapy among HNC patients on anxiety, depression and QoL. The result of study may add a valuable benefit for better HNC management outcomes.

3.4 MATERIAL AND METHODOLOGY

3.4.1. Study Design

This was a randomised clinical trial study, single-blinded study. The assessor who conducted the questionnaires was blinded to group assignment. The assessor was appointed among ORL Clinic staff. Blinding was not possible to principle investigator (PI) or participants, as both are directly exposed to the intervention (relaxation therapy and psychoeducation). The study was approved by the Medical Research and Ethics Committee of Universiti Sains Malaysia (Ethical no: USM/JEPeM/18120773) and was performed in adherence with the Declaration of Helsinki.

3.4.2. Study Area

This study was conducted in ORL Clinic and Psychiatric Rehabilitation Center @MENTARI of Hospital Universiti Sains Malaysia (Hospital USM). The study period started from April 2019 and ended in April 2020.

3.4.3. Study Population

Study population involved all HNC patients who were under follow up at ORL and Oncology Clinic in Hospital USM. The recruitment of patient into study was done using the list at ORL and Oncology Clinic.

The inclusion and exclusion criteria were as follow:

Inclusion criteria:

1. Patients age between 18-76 years old
2. Patient with stage II-IV HNC according to the staging system of the American Joint Committee on Cancer (AJCC 8th Edition)

3. HNC patients with any treatment status including pre-treatment, on-going or follow up phase

Exclusion criteria

1. Patient with underlying psychiatric disorder who are under psychiatric follow up (depression, anxiety)
2. Patient with evidence of brain metastasis, organic brain syndrome, delirium or psychosis
3. Patients with haemoglobin level less than 8g/dL
4. Patient who is terminally ill or dependent for activity of daily living (ADL)
5. Patient who are within 8 weeks prior to or post tumour resection surgery

The subjects' withdrawal from the study was amenable at any time without prejudiced to their care. They also may be discontinued from the study at the discretion of the investigator for lack of adherence to study plan and follow up. The investigator may also withdraw subjects who violates the study plan or to protect subject for reasons of safety or for administrative purposes.

Sample size calculation was done using G-Power Software Version 3.1.9.2 for specific objective #1 with proposed analysis using t-test giving the level of significant, α was 0.05; the power of study was equal to 80% and the effect size, f was 0.60. The sample size was 24 with dropout of 10% making the total sample was 26.

Patients with HNC who fulfill the selection criteria were recruited for this study during follow up at ORL or Oncology Clinic. They were given a comprehensive explanation regarding the study. Patients who consented to join this study were assigned randomly into study group or control group by using generated computerized randomization software (www.randomizer.org). Control group was given psychoeducation whereby the study group

received both psychoeducation and the relaxation therapy. An appointment was given to the participant in study group for relaxation therapy at Psychiatric Rehabilitation center @MENTARI. The psychoeducation was provided to the subject in control group on the same day of recruitment after patient had finished the clinic appointment. All subjects received a professional and standard care related to their illness without prejudice throughout the intervention period.

Patient's socio-demographic data and disease-related questionnaires were completed by the researcher based on patient's interview and medical record. Latest haemoglobin level taken during consultation at ORL or Oncology Clinic was reviewed from subjects' medical record. The haemoglobins status is important as anaemia in HNC is common and correlate with decline in QoL thus becoming the co-founder to the study³⁰.

Patients' age of 18-76 years with HNC stage II-IV were recruited for the study. Patients at any treatment status; pre-treatment, ongoing or follow up phase, were eligible for this study. The diversity of treatment status allowed the PI to investigate the effect of relaxation therapy as an adjunct to main treatment continuum in head and neck malignancy. However, those who were going for surgery or post-surgical treatment within 8 weeks of intervention period were excluded from the study to allow adequate preparation and full recovery respectively.

Those patients with low haemoglobin level below than 8g/dL were appropriately managed in relation to patient's anaemic status. Patients with underlying psychiatric disorder or under care of psychiatrist and those with evidence of brain metastases, organic brain syndrome, delirium or psychosis were excluded from the study. Terminally-ill or ADL-dependent patients were also disqualified from the study.

Both study and control group answered 2 sets of questionnaires which were Functional Assessment Cancer Therapy-Head & Neck version 4 (FACT-H&N) questionnaires for

assessment of QoL, and Hospital Anxiety and Depression Scale (HADS) for screening of anxiety and depression. The questionnaires were answered before the intervention for pre-test assessment. Later, the post-test assessment was performed at the completion of intervention period which was 6 weeks apart. The assessor has been appointed among medical staff at ORL Clinic to conduct the questionnaires session.

Psychoeducation was an intervention given to all subjects (study and control group) by PI regarding information and support to better understanding and coping with their illness. It focused on identification of patient's worry and process of thought ventilation related to HNC and treatment. Thus, information delivered included the nature of the HNC, causes, treatment, prognosis and expectation with regards to disease progress and treatment. This information helped the subject to develop a coping method. Psychoeducation was conducted one-to-one basis at week 1 and week 6 of intervention period at ORL Clinic for control group and at Psychiatric Rehabilitation Center @MENTARI for study group.

Relaxation therapy was given to subjects in study group. It involved 2 methods of relaxation technique which were deep breathing exercise and progressive muscular relaxation (PMR) technique. The relaxation therapy was held in relaxation room at Psychiatric Rehabilitation Center @MENTARI. The room was well decorated and furnished with chair, desk and bed. The therapy was given one-to-one basis.

Deep breathing exercise was a technique to relax by focusing the mind with the present moment whereby patient was aware of his/her own inhalation and exhalation of the air. The technique was demonstrated to the subject. It involved three steps. First step was breathing in slowly and deeply for five seconds by counting one, two, three, four and five. Secondly, holding the breath for similar five seconds then exhaling the breath out for another five seconds. During these steps, the subject felt the rise of the belly and chest and the movement of the ribs

to create the awareness of breathing sensation and focusing the mind on the present moment. The whole step would be repeated for 5 times.

PMR was a technique to elicit relaxation response by alternating tensing and then relaxing each major muscle group. Historically, it was first described by American physiologist Edmund Jacobson in 1920s²⁴. Before starting the procedure, the subject was given the description of the PMR and the aim of the procedure was to create a relaxation response of the body state. It was conducted in the relaxation therapy room in the comfortable condition. The light was dimmed according to the subject preference. The steps to be performed and the differences between the technique while doing in standing, sitting or lying down were demonstrated to subjects. Participant was instructed to contract and relax the muscles of their hands, forearms, face, neck, shoulders, abdomen, and lower limbs sequentially with each movement from tense to slack muscle took eight to ten seconds. The PMR techniques were performed in the following sequence:

- 1) fist the right hand tightly then release
- 2) fist the left hand tightly and then release
- 3) fist both hands and release
- 4) bend both elbows then straighten back
- 5) raise both the upper limbs until the pressure was felt on the shoulders
- 6) wrinkle the forehead and then relax
- 7) frown the eyebrows and then release
- 8) close the eyes and then open the eyes
- 9) push the tongue onto palate and then release
- 10) clench the teeth and then release
- 11) close the lips tightly and then release

- 12) push the head backward as far as possible, then turn to the right and left, afterwards return the head to its original position
- 13) lower the chin towards the chest
- 14) shrug the shoulders up
- 15) take a deep breath and exhale for three times
- 16) bend the upper body forward
- 17) contract the abdominal muscles
- 18) contract the lower back muscle and,
- 19) contract the foot muscle by dorsiflexion then relaxed.

Throughout the session, the subject was accompanied by a recorded audiotape of the steps which were explained prior to therapy. This technique enabled subject to recognize the large muscle tension during contraction and later appreciate the feeling of release of the tension.

There were 6 sessions of relaxation therapy which were implemented once per week. Each session took 30 minutes. 4 sessions (in week 1, 2, 4 and 6) have been conducted by PI at Psychiatric Rehabilitation Center @Mentari. PI demonstrated the relaxation technique and performed (deep breathing exercise and PMR) together with the subject. Other 2 sessions (in week 3 and 5) were self-conducted at home. A copy of steps of exercise in form of hard or soft copy was given to subjects.

The usage of relaxation room at Psychiatric Rehabilitation Center @Mentari did not disturb the main schedule of the centre. If there were any clash with clinic routine, priority was given to the clinic activity. The PI has liaised with the occupational therapist at Rehabilitation Centre regarding the conduction of the study.

3.4.4. Research Tool

1. Socio-demographic and cancer history questionnaire: The questions collected standard socio-demographic and disease-related information.
2. Functional Assessment Cancer Therapy-Head & Neck (FACT-H&N version 4) questionnaires.

QoL was measured using the FACT-H&N questionnaire version 4. The 37-item FACT-H&N consists of a 10-item head and neck cancer specific subscale (HN) appended to the oncology-specific QOL instrument. Each response is rated by the patient from 0 to 4 on a Likert scale, with 0 described as “not at all” and 4 as “very much.” Scores are calculated separately for each domain, and an unweighted summary score is calculated for the total FACT-H&N. The maximum score of 148 reflects the best possible quality of life. The maximal score for each domain is as follows: Physical 28, Social 28, Emotional 24, Functional 28, HN 40. FACT-H&N demonstrated reliability and validity, and was chosen following a structured review of the literature because it was commonly used, short, and provides a summary score for ease of analysis³¹. A clinically significant change in score on this instrument was represented by an increase of about 6 units or a decrease of about 12 units³². The FACT-H&N questionnaire has been translated and linguistically validated into Malay version and demonstrated acceptable cross-sectional construct validity, reliability and discriminative ability, and thus appear appropriate for further use among Malaysian¹⁵. Licensing agreement was obtained from FACIT.org to use the questionnaire for this study.

3. Hospital Anxiety and Depression Scale (HADS)

The HADS comprises two scales, one for depression (7 questions) and one for anxiety (7 questions). Cutoffs have been established to indicate when a patient probably (>10 points on 1 scale) or possibly (>7 points on 1scale) has psychiatric illness. The HADS questionnaire has been translated and linguistically validated into Malay language³³. The Malay version HADS questionnaires has shown a good sensitivity and specificity and therefore is valid instrument for use in a Malaysian population³³.

3.4.5. Outcome Measure

Data was analyzed using SPSS version 26. Descriptive statistics was used to summarize the socio-demographic and disease-related characteristics of subjects. Numerical data was presented as mean (SD) or median (IQR) based on their normality distribution. Categorical data was presented as frequency (percentage). The statistical analysis paired t-test was used to determine changes in anxiety, depression and QoL scores within group and independent t-test was used to compare differences between group. *P* value of 0.05 is considered statistically significant.