# ORIGINAL ARTICLE

# Effectiveness of a developed module in improving quality of life among breast cancer patients undergoing chemotherapy at Institut Kanser Negara

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**ABSTRACT**

**Introduction:** Cancer is one of the leading causes of morbidity and mortality worldwide. Breast cancer risk has risen due to lifestyle choices and genetic factors. Women with breast cancer symptoms experience lower quality of life (QoL), particularly in psychological and physical domains, compared to healthy women. Several studies reveal that poor QoL among breast cancer patients increases the risk of psychological distress. This study aimed to develop, implement, and evaluate the effectiveness of a counselling module in improving the QoL among breast cancer patients undergoing chemotherapy at the Institut Kanser Negara (IKN).

**Materials and Methods:** A single-blinded Randomized Controlled Clinical Trial was conducted at the IKN between January 2023 and June 2023. The estimated sample size was 120 participants. A sequential numbering system assigned a unique identifier to each participant until a total of 120 participants were recruited, with 60 participants in both the intervention and control groups. The intervention group received chemotherapy counselling using a newly developed module. QoL and depression were assessed at multiple time points using a validated questionnaire. Data were analysed using SPSS version 26, with independent tests and two-way repeated measures ANOVA. A p-value < 0.05 was considered significant, and partial eta squared was used to measure effect size.

**Result:** Overall, in age distribution, the intervention group had the highest percentage of participants in the 41-60 years category (40.0%), whereas the control group had the highest percentage of participants aged ≥61 years (38.3%). The counselling module was effective in improving QoL and depression among participants at baseline and for three consecutive follow-ups following interventions. The QoL showed improvement in all four domains in the intervention group, which were Physical Health (p < 0.001), Psychological (p < 0.001), Social Relationship (p < 0.001), and Environment (p = 0.001). There was also a moderate effect reduction on depression (p < 0.001).

**Conclusion:** The newly developed counselling module was effective in improving the QoL and depression among breast cancer patients. Repetitive counselling sessions by pharmacists, which were conducted during the module implementation, played a key role in ensuring the well-being of breast cancer patients throughout the treatment journey.

**KEYWORDS:**
*Cancer, chemotherapy, breast cancer, quality of life, depression*

## INTRODUCTION

Cancer, known as malignant tumors and neoplasms, occurs due to the uncontrolled growth of abnormal cells in the body.[1] It is one of the primary contributors to global mortality, responsible for nearly 10 million deaths in 2020.[2] That year, breast cancer diagnoses reached 2.3 million among women globally, resulting in 685,000 deaths. By the end of 2020, 7.8 million women who had been diagnosed with breast cancer in the previous five years were still alive, making it the most widespread cancer worldwide. Developed countries see higher breast cancer rates, and the incidence is rising almost everywhere.[1]

In Malaysia, cancer prevalence has risen over the past decade (2007-2016) among both men and women.[3] According to 2022 data from Global Cancer Observatory (GLOBOCAN), breast cancer accounted for the highest proportion (16.2%) of all new cancer cases in Malaysia, with 8,371 new cases diagnosed that year.[4] The Malaysian National Cancer Registry reported 115,238 new cancer cases between 2012 and 2016. Despite advanced health facilities, Malaysia's cancer mortality rate remains high. Breast cancer is the leading cause of cancer deaths among women in Malaysia, with the highest prevalence recorded among the Chinese ethnic population.[4] Chemotherapy, often combined with radiation or surgery, is the most common treatment for breast cancer.[5] Despite its benefits for survival, chemotherapy causes significant side effects, particularly impacting psychological health and physical well-being.[6,7]

Quality of life is a key measure of quality care in oncology.[8] Women with breast cancer symptoms experience lower QoL, particularly in psychological and physical domains, compared to healthy women.[9] Increased psychological distress negatively impacts illness perception and body

image.[10-12] Chemotherapy can further decline QoL and psychological health. Iddrisu et al. (2020) noted that some patients defaulted on their next chemotherapy cycle due to the disruptive effects on their daily routine.[13] Depression is a common psychological effect of chemotherapy among breast cancer patients, affecting about 20% of women.[14-16] Depression leads to emotional distress and significantly reduces QoL.[17-18]

Educational counselling has been shown to effectively manage cancer patients and mitigate some negative consequences of chemotherapy.[19] Iddrisu et al. (2020) recommended educating breast cancer patients on coping strategies and lifestyle activities to aid their recovery.[13] However, there are limited studies on educational interventions among breast cancer patients in Malaysia. This study aimed to develop, implement, and evaluate the effectiveness of a counselling module to improve the QoL of breast cancer patients undergoing chemotherapy at Institute Kanser Negara (IKN).

## MATERIALS AND METHODS
### Study Design and Setting
A randomised controlled trial (RCT) with a single-blinded study design was used in the study. This study was carried out at IKN. Participants were recruited from the oncology ward at the IKN. Eligible patients met the following criteria: (i) aged above 18; (ii) undergoing chemotherapy at the IKN; (iii) able to communicate verbally. Patients with language barriers or severe illnesses were excluded. The patients were randomly assigned into 2 groups by the pharmacist on duty for the day. The 2 groups consisted of the intervention group and control group. A total of 120 participants were randomly selected and allocated into intervention and control groups using a randomization method based on odd and even numbers, with each group consisting of 60 participants. The control group adhered to the standard IKN counselling protocol for breast cancer patients undergoing chemotherapy, while the intervention group received quality-of-life counselling using a specific module developed by a pharmacist. Data collection at IKN spanned six months, from January 2023 to July 2023. Counselling sessions for the intervention group began during their initial visit and continued through the first cycle of chemotherapy, with ongoing sessions up to the third follow-up appointment. Following a single-blinded approach, both groups were kept unaware of their assigned group. The effectiveness endpoints were evaluated over three consecutive chemotherapy cycles, with varying time intervals between each cycle ranging from 3 to 6 weeks. The study flow is depicted in Figure 1. A validated, pretested questionnaire was used to measure the QoL and depression at baseline, first follow-up, second follow-up, and third follow-up. Data were analysed using SPSS version 26. Independent tests were used to compare the variables at baseline. Two-way repeated measures ANOVA tests were used to assess the effectiveness of the intervention. A p-value of less than 0.05 was considered significant and partial eta squared was used to measure effect size.

### Intervention module
The newly developed intervention module, 'Improving Quality of Life in Breast Cancer Patients Undergoing Chemotherapy,' integrates components of QoL and Depression. The final version of the module was established after a pilot test conducted with breast cancer patients undergoing chemotherapy treatment, followed by a comprehensive review and revision by a panel of experts. The module provides an overview of key topics related to breast cancer and chemotherapy treatment. Chapter One covers the basics of breast cancer, chemotherapy, and dietary recommendations. Chapter Two focuses on chemotherapy drugs and their potential side effects. Chapter Three addresses managing physical side effects of chemotherapy, while Chapter Four discusses non-pharmacological techniques for coping with symptoms of depression. The primary objective of this module is to alleviate the depression levels experienced by breast cancer patients, ultimately improving their overall QoL. The module was implemented through repetitive pharmacist counselling following each cycle of chemotherapy for patients in the treatment group. Each counselling session lasted approximately 30-40 minutes per patient. These counselling sessions were conducted by pharmacist individually and face-to-face with patients, typically at their bedside, known as bedside counselling. Meanwhile, patients in the control group received counselling sessions using the hospital's existing counselling practices

### Questionnaire
This study employed a questionnaire consisting of sociodemographic data, including age, race, education, income, marital status, and cancer stage. The World Health Organization Quality of Life Brief Version (WHOQOL-BREF) questionnaire to assess the patient's QoL, comprising four domains: physical health, psychological, and social relationships, and environment. Each question in WHOQOL-BREF was scored from one to five, with higher scores indicating better evaluation. For depression assessment, the Patient Health Questionnaire (PHQ-9) was utilised, consisting of nine items derived from DSM-IV Criteria for Major Depressive Disorder. The PHQ-9 has demonstrated good sensitivity and specificity in detecting depression. These questionnaires were validated among the Malaysian population and are available in English and Malay languages.

### Data analysis
The data were entered into the statistical program SPSS version 26 (IBM SPSS Statistics 26, 2019). Analysis was done using descriptive and inferential statistical methods. An independent samples t-test was conducted to evaluate baseline differences between the intervention and control groups, as well as to compare changes in QoL domains and depression scores between the groups across the baseline, 1st counselling, 2nd counselling, and 3rd counselling sessions. The analysis of variance (ANOVA) test was utilised to examine the primary and interaction effects within and between groups concerning the average scores of QoL and depression. An analysis was undertaken to compare group times using multiple pairwise comparisons, which were conducted with a predetermined level of significance, denoted as alpha (α), set at 0.05 using the Bonferroni correction. This study's confidence interval (CI) was established at a 95% level, with a significance level of 0.05.

*Ethical consideration*
The ethical clearance for this study was obtained from the Medical Research and Ethics Committee (MREC) NMRR-20-3209-54195 (IIR), Ministry of Health Malaysia, and IKN. Each patient has distributed an information sheet about the study before data collection. Participants' participation was voluntary, and informed consent was obtained from them before the conduct of the study.

## RESULTS

Table I shows the baseline socio-demographic characteristics of both the intervention and control groups. In the age distribution analysis, the intervention group had the highest percentage of participants in the 41-60 years category (40.0%), whereas the control group had the highest percentage of participants aged ≥61 years (38.3%). Approximately 51.0% of participants in both groups identified as Chinese. Most participants in the intervention group (52.2%) and the control group (47.8%) were married. Regarding education levels, the majority of participants in the intervention group (56.6%) had no formal education or only primary education, while 43.2% had secondary education and 47.8% had tertiary education. In the control group, a higher percentage had secondary education (56.8%) compared to those with no formal/primary education (43.3%) and tertiary education (52.2%). Employment status was similar between groups, with 52.0% of participants in the intervention group and 48.0% in the control group being employed. Most households in both groups reported an income of less than RM 2,000.00. Most participants in both groups were in stage 2 of cancer and were undergoing their second and third cycles of chemotherapy. Many participants expressed concerns about chemotherapy-related pain and adverse effects, and most did not participate in cancer support groups. These characteristics were comparable between the two groups, with no statistically significant differences observed. Consequently, prior to the introduction of the intervention module, both groups displayed similar outcome measures.

*Effectiveness of the Newly Developed Intervention Module on Quality of Life*
Table II compares the mean scores for QoL and each domain between the intervention and control groups at baseline until the 3rd follow-up. At baseline, there were no statistically significant differences between physical health (p = 0.502), psychological (p = 0.260), social relationships p = 0.225), and environment (p = 0.725) between the intervention and control groups. Initially, there were no statistically significant differences in mean QoL ratings for Physical Health, Psychological Health, Social Relationships, and Environment between the intervention and control groups at baseline. For Physical Health, the intervention group showed a significant increase in mean scores at the first follow-up (M = 71.92, SD = 14.81), continuing to improve in the 2nd (M = 76.62, SD = 15.02) and 3rd (M = 79.30, SD = 14.63) follow-ups, remaining significantly higher than both baseline and control group levels (mean difference = 1.82, 95% CI = -3.53, 7.16, p = 0.502).

For Psychological Health, the intervention group exhibited significant improvement at the first follow-up (M = 60.92, SD = 15.27), with further positive changes in the 2nd (M = 63.00, SD = 14.89) and 3rd (M = 65.55, SD = 18.37) follow-ups. In contrast, the control group showed a significant decrease in mean Psychological Health scores from the first follow-up (M = 52.03, SD = 17.79) (mean difference = -3.35, 95% CI = -8.34, 1.63, p = 0.185).

For Social Relationships, the baseline differences were not statistically significant (mean difference = -5.31, 95% CI = -13.02, 2.40, p = 0.176). However, the intervention group showed a substantial improvement at the first follow-up (mean difference = -15.13, 95% CI = -22.7, -7.56, p < 0.001), which continued to the 2nd (mean difference = -27.6, 95% CI = -34.71, -20.48, p < 0.001) and 3rd follow-ups (mean difference = -33.47, 95% CI = -40.52, -26.42, p < 0.001).

For the Environment, no significant differences were noted at baseline (mean difference = -0.97, 95% CI = -4.46, 6.39, p = 0.725). However, significant improvements were seen in the intervention group at the first follow-up (M = 71.97, SD = 18.75), 2nd (M = 75.15, SD = 16.54), and 3rd follow-ups (M = 77.85, SD = 15.11). In contrast, the control group showed a significant decrease from the first follow-up (M = 54.57, SD = 17.45) onwards. Overall, the intervention group exhibited significant and sustained improvements across all QoL domains compared to the control group, highlighting the effectiveness of the intervention.

In Table III, the results of the two-way repeated measures ANOVA analysis for each domain of QoL on both groups (intervention and control) and time (baseline until 3rd follow-up) effects and interaction between group and time showed that; in physical health, there were significant main effects for the group ($F_{(1, 118)}$ = 22.952, p < 0.001, partial η2 = 0.163), Time ($F_{(3, 182.940)}$ = 10.472, p < 0.001, partial η2 = 0.082), and the interaction between group and time ($F_{(1.550, 182.940)}$ = 61.446, p < 0.001, partial η2 = 0.342); in psychological, there were significant main effects for group ($F_{(1, 118)}$ = 58.937, p < 0.001, partial η2 = 0.333), time ($F_{(1.555, 183.542)}$ = 5.181, p = 0.012, partial η2 = 0.042), and the interaction between group and time ($F_{(1.555, 183.542)}$ = 63.878, p < 0.001, partial η2 = 0.351). Regarding social relationship, there were significant main effects for group (($F_{(1, 118)}$ = 44.860, p < 0.001, partial η2 = 0.275); time ($F_{(1.678, 198.038)}$ = 10.465, p < 0.001, partial η2 = 0.081); and interaction between group and time ($F_{(1.678, 198.038)}$ = 173.392, p < 0.001, partial η2 = 0.595). Finally, in environment also, there were significant main effects for group Group ($F_{(1, 118)}$ = 65.327, p <0.001, partial η2 = 0.356), time ($F_{(1.872, 226.248)}$ = 7.174, p = 0.001, partial η2 = 0.057), and the interaction between group and time ($F_{(1.872, 226.248)}$ =129.437, p = <0.001, partial η2 = 0.523).

*Effectiveness of the Newly Developed Intervention Module on Depression*
Table IV compares the mean scores for depression between the intervention and control groups at baseline until 3rd follow-up. At baseline, there were no significant differences in depression (p = 0.749) between the intervention and control groups. Initially, no statistically significant differences in

**Table I: Baseline comparison of socio-demographic characteristics between the intervention and control groups (n=120)**

| Characteristics | Frequency, n (%) | | Total | Chi-square value | p-value |
|---|---|---|---|---|---|
| | Control group n=60 | Intervention group n=60 | | | |
| **1. Age** | | | | | |
| ≤40 | 15(42.9) | 20(57.1) | 35 | 2.058 | 0.357 |
| 41-60 | 22(47.8) | 24(52.2) | 46 | | |
| ≥ 61 | 23(59.0) | 16(41.0) | 39 | | |
| **2. Race** | | | | | |
| Malay | 21(45.7) | 25(54.3) | 46 | 1.491 | 0.684 |
| Chinese | 31(51.7) | 29(48.3) | 60 | | |
| Indian | 7(53.8) | 6(46.2) | 13 | | |
| Others | 1(100) | 0(0) | 1 | | |
| **3. Marital Status** | | | | | |
| Single | 14(53.8) | 12(46.2) | 67 | 1.214 | 0.545 |
| Married | 35(52.2) | 32(47.8) | 26 | | |
| Widowed/Divorced | 11(40.7) | 16(59.3) | 27 | | |
| **4. Education level** | | | | | |
| No formal education/primary | 30(56.6) | 23(43.3) | 53 | 1.786 | 0.409 |
| Secondary | 19(43.2) | 25(56.8) | 44 | | |
| Tertiary | 11(47.8) | 12(52.2) | 23 | | |
| **5. Working** | | | | | |
| Yes | 39(52.0) | 36(48.0) | 75 | 0.320 | 0.572 |
| No | 21(46.7) | 24(53.3) | 45 | | |
| **6. Monthly Income** | | | | | |
| No income | 21 (53.8) | 18(46.2) | 39 | 3.869 | 0.276 |
| ≤ 2000 | 23(59.0) | 16(41.0) | 39 | | |
| 2001-3500 | 11(37.9) | 18(62.1) | 29 | | |
| ≥3501 | 5 (38.5) | 8(61.5) | 13 | | |
| **7. Cancer Stage** | | | | | |
| Stage 1 | 23(54.8) | 19(45.2) | 42 | 0.844 | 0.656 |
| Stage 2 | 29(46.0) | 34(54.0) | 63 | | |
| Stage 3 | 8 (53.3) | 7(46.7) | 15 | | |
| **8. Number of Chemotherapy cycle** | | | | | |
| 1st cycle | 22(56.4) | 17(43.6) | 39 | 1.421 | 0.491 |
| 2nd cycle & 3rd cycle | 21(43.8) | 27(56.3) | 48 | | |
| 4th cycle & above | 17(51.5) | 16(48.5) | 33 | | |
| **9. Pain due to Chemotherapy** | | | | | |
| Yes | 48(49.5) | 49(50.5) | 97 | 0.054 | 0.817 |
| No | 12(52.2) | 11(47.8) | 23 | | |
| **10. Worried of adverse effect due to chemotherapy** | | | | | |
| Yes | 60 (100) | 60 (100) | 120 | 0 | - |
| **11. Joined Cancer Support Society** | | | | | |
| Yes | 1 (20.0) | 4 (80.0) | 5 | 1.878 | 0.171 |
| No | 59 (51.3) | 56 (48.7) | 115 | | |

* p <0.05

mean depression ratings were observed between the intervention and control groups at baseline (mean difference = 0.048, 95% CI = -0.345, 0.479, p = 0.749). However, at the first follow-up (M = 1.400, SD = 1.123) in the intervention group, a significant increase in mean score compared to the control group was observed in Depression. Positive significant changes were noted in the 2nd (M = 0.833, SD = 0.905) and 3rd (M = 0.617, SD = 0.993) follow-ups, with Depression scores remaining significantly higher than baseline and control group levels. In contrast, in the control group, Depression showed a significant decrease in mean score from the 1st follow-up (M = 1.883, SD = 1.151) followed by subsequent follow-ups. In Table V the results of the two-way repeated measures ANOVA analysis for depression on both groups (intervention and control) and time (baseline, until 3rd follow-up) effects and interaction between group and time showed that there were significant main effects for the group

(F (1, 118) = 94.519, p < 0.001, partial η2 = 0.158) and the interaction between group and time (F (1.997, 241.72) = 72.539, p < 0.001, partial η2 = 0.381). Additionally, there were significant findings for time (F (2.502, 241.72) = 10.383, p <0.001, partial η2 = 0.381). These results suggest that depression levels varied across different time points, independent of the intervention effect.

## DISCUSSION
*QoL*
The QoL in the present study was evaluated through four domains (Physical health, Psychological, Social relationship, and Environment). A study showed that patient information on the side effects of chemotherapy treatment is essential and should be an important part of supportive care. Especially in palliative care settings, where symptom control is the main

**Table II: Comparison of mean score changes in quality of life between intervention and control groups across three follow-up assessments**

| Outcome measures | Mean ± SD | | Mean difference (95%CI) | T statistic (df) | p-value |
|---|---|---|---|---|---|
| | Intervention group (n=60) | Control group (n=6) | | | |
| **Physical Health** | | | | | |
| Baseline | 63.28±14.51 | 65.10±15.05 | 1.82 (-3.53, 7.16) | 0.673(118) | 0.502 |
| 1st follow-up | 71.92±14.81 | 60.98±14.78 | -10.93 (-16.28, -5.59) | -4.048(118) | <0.001** |
| 2nd follow-up | 76.62± 15.02 | 59.60±14.79 | -17.02 (-22.41, -11.63) | -6.253(118) | <0.001** |
| 3rd follow-up | 79.30± 14.63 | 58.33±14.38 | -20.97 (-26.21, -15.72) | -7.917(118) | <0.001** |
| **Psychological** | | | | | |
| Baseline | 59.15±12.55 | 56.23±15.53 | -2.917 (-8.022, 2.189) | -1.13(118) | 0.260 |
| 1st follow-up | 60.92±15.27 | 52.03±17.79 | -8.883 (-14.877, -2.890) | -2.94(118) | 0.004* |
| 2nd follow-up | 63.00±14.89 | 41.22±17.18 | -21.783 (-27.596, -15.970) | -7.42(118) | <0.001** |
| 3rd follow-up | 65.55±18.37 | 36.88±15.26 | -28.667 (-34.770, -22.563) | -9.30(118) | <0.001** |
| **Social relationships** | | | | | |
| Baseline | 63.12±20.44 | 58.87±17.59 | -4.25 (-11.14, 2.64) | -1.22(118) | 0.225 |
| 1st follow-up | 67.28±18.89 | 50.73±17.67 | -16.55 (-23.16, -9.94) | -4.96(118) | <0.001** |
| 2nd follow-up | 71.77±16.74 | 44.10±16.56 | -27.67 (-33.69, -21.65) | -9.10(118) | <0.001** |
| 3rd follow-up | 74.18±15.37 | 40.60±15.44 | -33.58 (-39.15, -28.02) | -11.94(118) | <0.001** |
| **Environment** | | | | | |
| Baseline | 61.37±17.40 | 62.33±12.14 | 0.97(-4.46, 6.39) | 0.353(118) | 0.725 |
| 1st follow-up | 71.97±18.75 | 54.57±17.45 | -17.4 (-23.95, -10.85) | -5.262(118) | <0.001** |
| 2nd follow-up | 75.15±16.54 | 43.77±15.40 | -31.38 (-37.16, -25.60) | -10.755(118) | <0.001** |
| 3rd follow-up | 77.85±15.11 | 40.13±15.59 | -37.72 (-43.27, -32.16) | -13.451(118) | <0.001** |

* p < 0.05, ** p < 0.001

therapeutic aim, the impact of treatment on QoL is important to be monitored as well. The present study showed that there was a significant improvement in this study's QoL in all domains (Physical health, Psychological, Social relationship, and Environment) and improved over time with repetitive counselling among patients in the intervention group. In comparison to the control group, there were significant increases in the QoL during the subsequent follow-ups. The present study showed that patients who had depression were associated with poor QoL. A randomized control study supported the present study, where continuous counselling by pharmacists improved the QoL of cancer patients undergoing chemotherapy. Another study also mentioned that the QoL and emotional well-being significantly improved among breast cancer patients who underwent group therapy intervention.[20] The study also reported that group therapy reduced the depression level among breast cancer patients, and the QoL was enhanced.[21] Adding on to that, a prospective observational single-center cohort study was conducted among early-stage breast cancer patients where depression and QoL were measured among the breast cancer patients, and a dynamic change in depression and QoL was observed when monitoring the depression level and support for breast cancer patients.[22]

*Depression*
In this study, there were no significant differences in depression between the intervention and control groups at baseline. These percentages include mild, moderate, and severe depression. Depression is a common comorbidity in cancer patients, with a prevalence rate ranging from 15% to 50% according to various studies.[23-25] For example, a systematic review conducted in 2017 aimed to assess the levels of depression among Iranian women diagnosed with breast cancer found that while mild depression was present, 69.4% of participants had serious levels of depression.[26]

In this current study, the intervention group that received repetitive counselling showed significant improvement in depression levels, with a decrease in mean scores over time. Compared to the control group, the intervention group exhibited substantial decreases in depression severity during subsequent follow-up assessments. Spending quality time with patients and engaging in frequent interactions were beneficial in fostering a positive attitude toward disease management. Moreover, the involvement of pharmacists presented an opportunity to impact both the patients' well-being and treatment outcomes positively. For instance, a study by Umma mentioned that chemotherapy counselling conducted by a pharmacist significantly improved the QoL and psychological outcomes of oncology patients undergoing treatment in Malaysia.[19] This underscores the critical role pharmacists play in supporting cancer patients' emotional well-being and enhancing their overall treatment experience.[19]

Another study revealed that incorporating psychosocial interventions, such as counselling, is a vital component of comprehensive cancer care.[27] These intervention help address the emotional well-being of cancer patients, improve their QoL, enhance coping strategies, and reduce the burden of depression during their cancer journey.[27] Additionally, a study by Vimala (2012) also revealed that cancer patients are invariably exposed to psychosocial stress due to the disease and the treatment strategy.[28] Implementing counselling practices can prepare cancer patients to manage depression and psycho-social challenges better.[27]

*The significance of repetitive counselling by pharmacists among breast cancer patients undergoing chemotherapy*
A pharmacist can be a valuable information hub for families navigating cancer treatments. Having a fundamental grasp of various chemotherapy types and the reasons behind side

**Table III: Effectiveness of intervention module on quality of life between intervention and control groups over time**

| Source | Type III Sum of Squares | df | Mean square | F | p-value | Partial η2 |
|---|---|---|---|---|---|---|
| **Physical Health** | | | | | | |
| Group | 16638.075 | 1 | 16638.075 | 22.952 | < 0. 001** | 0.163 |
| Error (Between) | 85537.792 | 118 | 724.897 | | | |
| Time | 1520.517 | 3 | 980.765 | 10.472 | <0.001** | 0.082 |
| Group*Time | 8922.108 | 1.550 | 5754.944 | 61.446 | <0.001** | 0.342 |
| Error (within) | 17133.875 | 182.940 | 93.658 | | | |
| **Psychological** | | | | | | |
| Group | 35793.802 | 1 | 35793.802 | 58.937 | <0.001** | 0.333 |
| Error (Between) | 71663.696 | 118 | 607.319 | | | |
| Time | 1509.323 | 1.555 | 970.352 | 5.181 | 0.012* | 0.042 |
| Group*Time | 18607.773 | 1.555 | 11963.041 | 63.878 | <0.001** | 0.351 |
| Error (within) | 34373.654 | 183.542 | 187.280 | | | |
| **Social Relationships** | | | | | | |
| Group | 50491.519 | 1 | 50491.519 | 44.860 | <0.001** | 0.275 |
| Error (Between) | 132813.563 | 118 | 1125.539 | | | |
| Time | 909.290 | 1.678 | 541.795 | 10.465 | <0.001** | 0.081 |
| Group*Time | 15065.973 | 1.678 | 8976.971 | 173.392 | <0.001** | 0.595 |
| Error (within) | 10252.988 | 198.038 | 51.773 | | | |
| Group | 54869.633 | 1 | 54869.633 | 65.327 | <0.001** | 0.356 |
| **Environment** | | | | | | |
| Group | 54869.633 | 1 | 54869.633 | 65.327 | <0.001** | 0.356 |
| Error (Between) | 99110.233 | 118 | 839.917 | | | |
| Time | 1466.817 | 1.872 | 783.493 | 7.174 | <0.001** | 0.057 |
| Group*Time | 26465.017 | 1.872 | 14136.160 | 129.437 | <0.001** | 0.523 |
| Error (within) | 24126.667 | 226.248 | 106.638 | | | |

*p < .05, **p < .001

**Table IV: Comparison of mean score changes in depression between intervention and control groups across three follow-up assessments**

| Outcome measures | Mean ± SD | | Mean difference (95%CI) | T statistic (df) | p-value |
|---|---|---|---|---|---|
| | Intervention group (n=60) | Control group (n=60) | | | |
| Baseline | 1.733±1.102 | 1.800±1.176 | 0.067 (-0.345, 0.479) | 0.320(118) | 0.749 |
| 1st follow-up | 1.400±1.123 | 1.883±1.151 | 0.483 (0.722, 0.894) | 2.328(118) | 0.022* |
| 2nd follow-up | 0.833±0.905 | 2.050±1.126 | 1.217 (0.8477, 1.586) | 6.522(118) | <0.001** |
| 3rd follow-up | 0.617±0.993 | 2.400±1.304 | 1.783 (1.364,2.203) | 8.426(118) | <0.001** |

*p < .05, **p < .001

**Table V: Effectiveness of intervention module on depression between intervention and control groups over time**

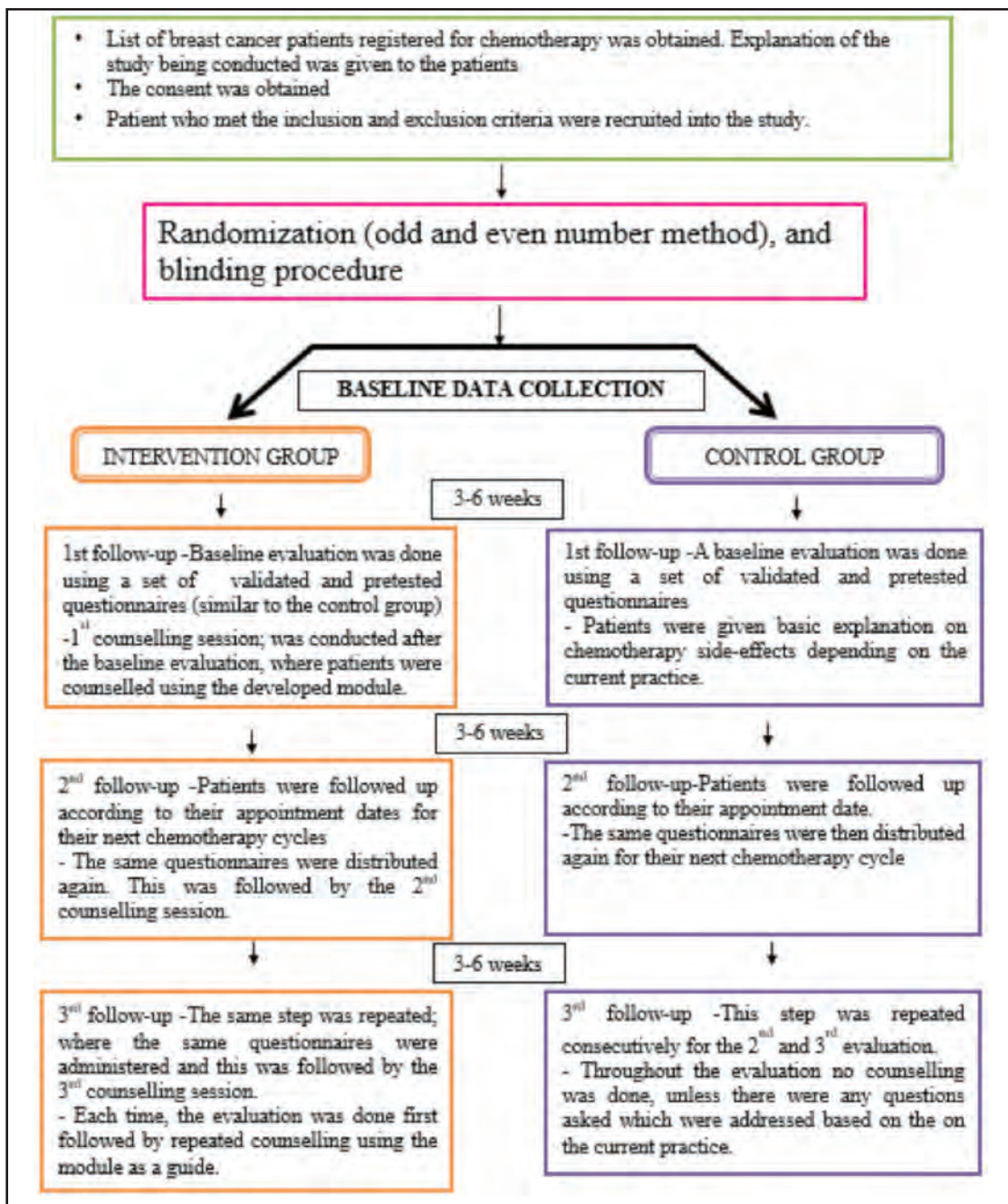| Source | Type III Sum of Squares | df | Mean square | F | p-value | Partial η2 |
|---|---|---|---|---|---|---|
| Group | 94.519 | 1 | 94.519 | 22.201 | <0.001** | 0.158 |
| Error (Between) | 502.379 | 118 | 4.257 | | | |
| Time | 7.506 | 3 | 2.502 | 10.383 | <0.001** | 0.381 |
| Group*Time | 52.440 | 1.997 | 26.260 | 72.539 | <0.001** | 0.381 |
| Error (within) | 85.304 | 241.72 | 0.362 | | | |

*p < .05, **p < .001

**Fig. 1:** CONSORT diagram of the study participants

effects is essential for effectively conveying this information to patients. Additionally, being well-versed in prevalent side effects, both in terms of pharmacological and non-pharmacological management, as well as understanding when to refer patients to physicians and the significance of support groups, are all pivotal aspects. Across numerous countries, the role of pharmacists is shifting from conventional drug-centred services to patient-centric services. This shift includes providing detailed information about chemotherapy regimens and potential side effects to individuals undergoing cancer treatment.[29] These findings align with previous research, suggesting that consistent and ongoing counselling, support, and patient care indirectly enhance mental and physical recovery.

Pharmacists play a distinct role in partnering with healthcare experts to enhance patient care. Furthermore, research has shown that continuous counselling by pharmacists improves the QoL among cancer patients undergoing chemotherapy.[20,30] The introduction of counselling sessions at the outset of systemic therapy has been associated with improved QoL outcomes. Consequently, it is recommended that pharmacists implement regular counselling sessions during cancer patients' treatment to effectively enhance their QoL both during and after the treatment period These results hold valuable implications for preserving patients' QoL throughout their cancer treatment journey.[30] Pharmacists should play a pivotal role in treating and caring for cancer patients, functioning as an integral part of the crucial

interdisciplinary oncology team. This was similarly concluded in a study where pharmacists provided continual counselling led to an enhancement in the QoL among cancer patients undergoing chemotherapy.[20] The introduction of counselling by pharmacists at the outset of systemic therapy led to improved QoL. Consequently, it is recommended that pharmacists implement counselling sessions during cancer patients' treatment to effectively enhance their QoL both during and after the treatment period.[20]

## RECOMMENDATIONS

This module shows promise for hospital implementation, particularly for breast cancer patients undergoing chemotherapy. It can enhance QoL and manage depression associated with chemotherapy. The module's guidance enables pharmacists to spend quality time with each patient, addressing the psychological effects of chemotherapy and improving overall QoL. Incorporating repetitive counselling sessions at regular intervals allows for ongoing monitoring of the intervention's impact. Given the module's demonstrated effectiveness, it could be proposed to Pharmacy Practice & Development Division, Ministry of Health, Malaysia for further research and broader implementation in clinical practice. The outcomes of this study suggest avenues for further research. Future studies should use a larger sample size to better assess side effects and depression management among breast cancer patients undergoing chemotherapy. Extending the intervention duration and incorporating caregiver support could clarify its impact. Additionally, a multisite study with a more diverse population would enhance heterogeneity and reduce cross-contamination, preserving the findings' internal validity.

This study's findings can aid future researchers in identifying the specific needs of cancer patients undergoing chemotherapy. It highlights the importance for health professionals to consider factors impacting chemotherapy patients' QoL. However, a limitation is that the study only included patients from one centre, potentially limiting generalizability. Also, due to time constraints, the study only followed up on the first three chemotherapy cycles. Stage 4 cancer patients, who are often in palliative care, were excluded due to the self-administered questionnaire's nature, which could pose participation challenges. Despite these limitations, the study underscores the significance of counselling for breast cancer patients undergoing chemotherapy. The findings demonstrate the value of implementing counselling interventions to consistently monitor and enhance QoL during treatment.

## CONCLUSION

The newly developed counselling module was effective in improving the QoL among breast cancer patients undergoing chemotherapy at the IKN. Notably, this study marks one of the pioneering efforts in Malaysia, as it evaluates the effectiveness of repetitive chemotherapy counselling conducted by pharmacists among breast cancer patients. The outcomes of this study hold significant value and relevance for breast cancer patients, as they present a way to uphold QoL throughout the chemotherapy treatment. Due to that, it is suggested to propose repetitive counselling sessions by pharmacists during the treatment of cancer patients, with the objective of enhancing their QoL both during and after the chemotherapy treatment.

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