ORIGINAL ARTICLE

Evaluating the Impact of an Intervention Module on Reducing Physical Side Effects in Breast Cancer Patients Undergoing Chemotherapy

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ABSTRACT

Introduction: Cancer remains one of the leading causes of morbidity and mortality worldwide, with breast cancer being one of the most prevalent forms affecting women globally. This study aims to develop, implement, and evaluate the effectiveness of an intervention module designed to reduce the physical effects experienced by breast cancer patients undergoing chemotherapy at the Institute Kanser Negara (National Cancer Institute). Methods: A single-blinded Randomized Controlled Clinical Trial was conducted at Institut Kanser Negara between January 2023 and Jun 2023. The estimated sample size was 120 participants, with 60 participants in both the intervention and control groups. The intervention group received chemotherapy counseling using a newly developed module over three chemotherapy cycles. Result: The counselling module was effective in reducing the physical side effects among breast cancer patients undergoing chemotherapy at baseline and for three consecutive follow-ups . There was also a moderate effect reduction for physical side effects such as nausea ($p< 0.001$, partial $\eta 2 = 0.522$), vomiting ($p < 0.001$, partial $\eta 2 = 0.519$), diarrhea ($p < 0.001$, partial $\eta 2 = 0.389$), constipation ($p < 0.001$, partial $\eta 2 = 0.226$), fatigue ($p < 0.001$, partial $\eta 2 = 0.319$), hair loss ($p = 0.256$, partial $\eta 2 = 0.011$), mouth, gum and throat infection ($p < 0.001$, partial $\eta 2 = 0.237$), skin and nail changes ($p <0.001$, partial $\eta 2 = 0.145$). Conclusion: The intervention module with repetitive counseling sessions conducted by a pharmacist effectively reduced physical side effects in breast cancer patients undergoing chemotherapy.
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INTRODUCTION

The incidence and prevalence of breast cancer have been increasing across Asian nations (1). In the year 2020, breast cancer diagnoses reached 2.3 million among women globally, leading to 685,000 deaths. By the end of 2020, there were 7.8 million women alive who had been diagnosed with breast cancer within the previous five years, making it the most common cancer worldwide (1). In Malaysia, the Malaysian National Cancer Registry (MNCR) reported a significant increase in cancer cases, with 115,238 new cases recorded between 2012 and 2016. Despite Malaysia's advanced healthcare facilities, the cancer mortality rate remains high. The prevalence of cancer has shown an increasing trend over the past decade (2007-2016) among both male and female Malaysians. Notably, breast cancer has been the primary cause of cancer-related deaths among females in Malaysia, with the highest prevalence recorded among the Chinese population (2).

Chemotherapy remains the most widely used treatment modality for breast cancer, often in combination with radiation or surgical therapy. Despite its efficacy in improving survival rates, chemotherapy is associated with numerous side effects that significantly impact patients' psychological and physical well-being (3, 4). These adverse effects can lead to a diminished quality of life (QOL), considered a primary endpoint measure for quality care and management in oncology (5). Women experiencing breast cancer symptoms often report lower QOL, particularly in psychological and physical domains, compared to healthy women in the population (6). According to Iddrisu et al. (7), some patients have defaulted on subsequent chemotherapy cycles due

to their inability to cope with the impact of cancer treatment on their daily lives.

Educational counseling has recently been identified as an effective intervention for managing cancer patients and mitigating the negative consequences associated with chemotherapy (8). Iddrisu et al. (7) emphasize the importance of engaging breast cancer patients in educational programs that teach coping strategies and lifestyle adjustments to aid their recovery journey. Similarly, Dang (9) highlights the crucial role of providing patients with detailed information about their treatment and potential side effects, which significantly helps them manage chemotherapy complications.
Despite the recognized benefits of educational interventions, there is a lack of research focusing on this approach among breast cancer patients in Malaysia. Thus, this study aims to address this gap by developing, implementing, and evaluating the effectiveness of an intervention counseling module designed to reduce physical side effects among breast cancer patients undergoing chemotherapy at Institut Kanser Negara (National Cancer Institute). This research aims to provide valuable insights into alleviating the physical side effects of chemotherapy for breast cancer patients in Malaysia through targeted educational support.

CONCLUSION

The incidence and prevalence of breast cancer have been increasing across Asian nations (1). In the year 2020, breast cancer diagnoses reached 2.3 million among women globally, leading to 685,000 deaths. By the end of 2020, there were 7.8 million women alive who had been diagnosed with breast cancer within the previous five years, making it the most common cancer worldwide (1). In Malaysia, the Malaysian National Cancer Registry (MNCR) reported a significant increase in cancer cases, with 115,238 new cases recorded between 2012 and 2016. Despite Malaysia's advanced healthcare facilities, the cancer mortality rate remains high. The prevalence of cancer has shown an increasing trend over the past decade (2007-2016) among both male and female Malaysians. Notably, breast cancer has been the primary cause of cancer-related deaths among females in Malaysia, with the highest prevalence recorded among the Chinese population (2).

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MATERIALS AND METHODS

Study Design and Setting

A randomized controlled trial (RCT) with a single-blinded study design was conducted at IKN. Participants were recruited from the Oncology Ward at IKN. Eligible patients met the following criteria: (i) aged above 18, (ii) undergoing chemotherapy at IKN, and (iii) able to communicate verbally. Patients with language barriers or severe illnesses were excluded. The patients were randomly assigned into two groups by the pharmacist on duty. These groups comprised the intervention group and the control group. 120 patients were randomly selected and allocated into intervention and control groups using a single-blind and randomization (odd and even number) method. The control group adhered to the standard IKN counselling protocol for breast cancer patients undergoing chemotherapy, while the intervention group is counselled using the newly developed counselling module. 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. A validated, pretested questionnaire was used to measure physical side effects 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. Generalised Linear Model (GLM) 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 as a measure of effect size.

Study tool

Intervention module

The newly developed intervention module, titled 'Chemotherapy Counselling: Improving Quality of Life for Breast Cancer Patients' was designed to primarily address and mitigate the physical side effects induced by chemotherapy, thereby enhancing the overall quality of life for breast cancer patients. This module was developed based on Orem's (1995) Self-Care Theory, which emphasizes self-empowerment, enabling patients to effectively manage their health. This proposed module was implemented after each chemotherapy cycle for the intervention group. The module comprised four chapters focusing on self-care and managing chemotherapy side effects. Patients in the treatment group received repetitive chemotherapy counseling based on this module, with support for physical side effects and depressive symptoms due to chemotherapy from baseline to the third follow-up. Each session, lasting 30–40 minutes, aimed to enhance quality of life (QOL) for breast cancer patients. Pharmacists provided one-on-one bedside counseling, ensuring confidentiality to prevent interference between groups. Conversely, patients in the control group receive chemotherapy counseling according to the hospital's standard practices.

Questionnaires

A questionnaire collected demographic data, including age, race, education, income, marital status, and cancer stage. The Common Terminology Criteria for Adverse Events (CTCAE) version 4.0 questionnaire (2009) featured several adverse events such as nausea, vomiting, diarrhoea, constipation, fatigue, hair loss, mouth, gum and throat infection, and skin and nail alterations (29) . These questionnaires were validated among the Malaysian population and are available in both English and Malay. The reliability obtained for Physical Side Effects questionnaire was 0.70, indicating an acceptable level of internal consistency.

Data Analysis

Data were entered into SPSS version 26 (IBM SPSS Statistics 26, 2019) for descriptive and inferential statistical analysis. An independent samples t-test was employed to evaluate any statistically significant differences between the groups or associations between variables at baseline. Additionally, the independent samples t-test was used to determine changes in responses to the intervention across each physical effect of chemotherapy from baseline through the 1st, 2nd, and 3rd counseling sessions. The two-way repeated measures ANOVA or Generalized Linear Model (GLM) was used to analyze the main and interaction effects within and between groups on the average scores of chemotherapy-related physical side effects. With the Bonferroni correction applied, multiple pairwise comparisons were conducted to compare group times, using a predetermined significance level (alpha, α) set at 0.05. The confidence interval (CI) for this study was set at 95%, with a significance level of 0.05.

Ethics consideration

Ethical clearance for this study was obtained from the Medical Research and Ethics Committee (MREC) under approval number NMRR-20-3209-54195 (IIR), Ministry of Health Malaysia, and the Universiti Putra Malaysia (UPM) Ethics Committee for Research Involving Human Subjects (Jawatankuasa Etika Universiti untuk Penyelidikan Melibatkan Manusia, JKEUPM). Additionally, permission was obtained from the Institute Kanser Negara (IKN) prior to the commencement of the study. An information sheet about the study was distributed to each patient before data collection. Participation was voluntary, and informed consent was obtained from all patients before the study began. All personal details and questionnaires were treated with strict confidentiality. After the project was completed, the intervention program, which involved counseling using the intervention module, was also offered to patients in the control group.

RESULTS

Table I presents the baseline socio-demographic characteristics of the intervention and control groups. These characteristics were comparable between the two groups, with no significant differences noted. This similarity ensured that before introducing the intervention module, both groups had similar outcome measures. In the age distribution analysis, the highest percentage of participants in the intervention group fell within the 41-60 years category (40.0%), while the control group had the highest percentage of participants aged 61 years and older (38.3%). Approximately 51.0% of participants in both groups identified as Chinese. The majority of participants were married, with 52.2% in the intervention group and 47.8% in the control group. Additionally, 60.0% of participants in both groups had attended at least upper secondary school. Regarding employment, 52.0% of participants in the intervention group and 48.0% in the control group were employed. Furthermore, most households in both groups reported a monthly income of less than RM 2,000.00. The majority of participants in both groups were in stage 2 of cancer and were undergoing their second cycle of chemotherapy. Almost 81% of participants expressed concerns about chemotherapy-related pain and all participants were worried of adverse effects due to chemotherapy. Additionally, most participants in both groups did not participate in cancer support groups.

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

Characteristics	Frequency, n (%)		Total N=120	Chi square value	p-value
	Control group n=60	Intervention group n=60			
1. Age(years)					
≤40	15(25.0)	20(33.3)	35		
41-60	22(36.7)	24(40.0)	46	2.058	0.357
≥ 61	23(38.3)	16(26.7)	39		
2. Race					
Malay	21(35.0)	25(41.7)	46		
Chinese	31(51.7)	29(48.3)	60	1.491	0.684
Indian	7(11.7)	6(10.0)	13		
Others	1(1.6)	0(0)	1		
3. Marital Status					
Single	14(23.3)	12(20.0)	26		
Married	35(58.3)	32(53.3)	67	1.214	0.545
Widowed/Divorced	11(9.2)	16(26.7)	27		
4. Education level					
No formal education/primary	6(10.0)	3(5.0)	9		
Secondary	24(40.0)	20(33.3)	44	2.095	0.351
Tertiary	30(50.0)	37(61.7)	67		
5. Working					
Yes	39(65.0)	36(60.0)	75	0.320	0.706
No	21(46.7)	24(40.0)	45		
6. Monthly Income (RM)					
≤ 2000	28(46.7)	32(53.3)	60		
2001-3500	26(43.3)	19(31.7)	45	1.956	0.376
≥3501	6 (40.0)	9(15.0)	15		
7. Cancer Stage					
Stage 1	23(38.3)	19(31.7)	42		
Stage 2	29(48.3)	34(56.7)	63	0.844	0.656
Stage 3	8 (13.3)	7(11.7)	15		
8. Number of Chemotherapy cycle					
1st cycle	22(36.7)	17(28.3)	39		
2nd cycle & 3rd cycle	21(35.0)	27(45.0)	48	1.421	0.491
4th cycle & above	17(28.3)	16(26.7)	33		
9. Pain due to Chemotherapy					
Yes	48(80.0)	49(81.7)	97		
No	12(20.0)	11(18.3)	23	0.054	>0.999
10. Worried of adverse effect due to chemo therapy					
Yes	60 (100)	60 (100)	120	0	
11. Joined Cancer Support Society					
Yes	1 (1.7)	4 (6.7)	5		
No	59 (98.3)	56(93.3)	115	1.878	0.364

Table II shows the physical side effects outcome, comparing the intervention and control groups at baseline. No significant differences were observed between the intervention and control groups across all outcome measures at baseline. As a result, both groups displayed similar baseline characteristics in their outcome measures before the implementation of the developed intervention module for participants in the intervention group.

Table II : Baseline comparison of physical side effects between the intervention and control groups.

Outcome measures	Frequency, n (%)			Chi-square value	p-value
	Control n=60	Intervention n=60	Overall n=120		
Physical effects					
Nausea					
None	4(6.7)	10(16.7)	14		
Mild	31(51.7)	26(43.3)	57	3.194	0.363
Moderate	18(30.0)	16(26.7)	34		
Severe	7(11.6)	8(13.3)	15		
Vomiting					
None	11(18.3)	7(11.7)	18		
Mild	20(33.3)	24(40.0)	44	4.153	0.245
Moderate	23(38.3)	17(28.3)	40		
Severe	6(10.0)	12(20.0)	18		
Diarrhea					
Mild	10(16.7)	7(11.7)	17		
Moderate	32(53.3)	42(70.0)	74	3.570	0.168
Severe	18(30.0)	11(18.3)	29		
Constipation					
None	9(15.0)	2(3.3)	11		
Mild	15(25.0)	13(21.7)	28	6.787	0.790
Moderate	14(23.3)	23(38.3)	37		
Severe	22(36.7)	22(36.7)	44		
Fatigue					
None	1(1.7)	6(10.0)	7		
Mild	29(48.3)	24(40.0)	53	5.060	0.167
Moderate	30(50.0)	29(48.3)	59		
Severe	0(0)	1(1.7)	1		
Hair Loss					
Mild	5(8.3)	6(10.0)	11		
Moderate	26(43.3)	28(46.7)	54	0.329	0.848
Severe	29(48.3)	26(43.3)	55		
Mouth, gum and throat infection					
None	14(23.3)	17(28.3)	31		
Mild	22(36.7)	15(25.0)	37	3.436	0.329
Moderate	23(38.3)	24(40.0)	47		
Severe	1(1.7)	4(6.7)	5		
Skin, and nail changes					
None	7(11.7)	13(21.7)	20		
Mild	37(61.7)	24(40.0)	61	6.861	0.076
Moderate	14(23.3)	17(28.3)	31		
Severe	2(3.3)	6(10.0)	8		

***Significant at p <0.05**

Effectiveness of the Newly Developed Intervention Module on physical side effects.

Table III presents the results of the two-way repeated measures ANOVA analysis for each physical side effect on both groups (intervention and control) and time (baseline until 3rd follow-up) effects and interaction between group and time. To address the violation of sphericity (Mauchly's test ($\chi 2$), $p < 0.001$), Greenhouse-Geiser adjusted estimations were utilized for data interpretation. These findings show a significant difference between the intervention and physical side effects over time, except for hair loss.

Table III : Effectiveness of Intervention Module on Physical effects Between Intervention and Control Groups Over Time

Source	Type III Sum of Squares	df	Mean square	F	p-value	Partial η^2
Nausea						
Group	117.019	1	117.019	52.677	<0.001**	0.309
Error (Between)	262.129	118	2.221			
Time	1.473	2.660	0.554	3.282	0.026*	0.027
Group*Time	57.823	2.660	21.739	128.849	<0.001**	0.522
Error (within)	52.954	313.866	0.169			
Vomiting						
Group	72.852	1	72.852	29.456	<0.001**	0.200
Error (Between)	291.846	118	2.473			
Time	1.490	2.820	0.528	3.062	0.031*	0.025
Group*Time	61.856	2.820	21.936	127.152	<0.001**	0.519
Error (within)	57.404	332.741	0.173			
Diarrhea						
Group	108.300	1	108.300	129.357	<0.001**	0.523
Error (Between)	98.792	118	0.837			
Time	10.208	2.608	3.914	16.387	<0.001**	0.122
Group*Time	46.783	2.608	17.937	75.099	<0.001**	0.389
Error (within)	73.508	307.760	0.239			
Constipation						
Group	72.075	1	72.075	31.688	<0.001**	0.212
Error (Between)	268.392	118	2.275			
Time	17.617	1.540	11.443	9.269	0.001**	0.073
Group*Time	65.608	1.540	42.615	34.519	<0.001**	0.226
Error (within)	224.275	181.668	1.235			
Fatigue						
Group	63.075	1	63.075	52.042	<0.001 **	0.306
Error (Between)	143.017	118	1.212			
Time	4.025	2.467	1.632	8.998	<0.001 **	0.071
Group*Time	24.692	2.467	10.009	55.200	<0.001 **	0.319
Error (within)	52.783	291.099	0.181			
Hair loss						
Group	0.208	1	0.208	0.107	0.744	0.001
Error (Between)	229.292	118	1.943			
Time	4.283	1.554	2.757	9.095	0.001	0.072
Group*Time	0.642	1.554	0.413	1.362	0.256	0.011
Error (within)	55.575	186.907	0.303			

CONTINUE

Source	Type III Sum of Squares	df	Mean square	F	p-value	Partial η^2
Mouth gum throat infection						
Group	10.208	1	10.208	4.306	0.040	0.035
Error (Between)	279.758	118	2.371			
Time	2.050	2.369	0.865	6.102	0.001	0.049
Group*Time	12.308	2.369	5.195	36.638	<0.001	0.237
Error (within)	39.642	279.558	0.142			
Skin nail changes						
Group	8.008	1	8.008	3.971	0.049	0.033
Error (Between)	237.958	118	2.017			
Time	1.550	2.253	0.688	4.116	0.014*	0.034
Group*Time	7.508	2.253	3.333	19.936	<0.001**	0.145
Error (within)	44.442	265.846	0.167			

Regarding hair loss, both the intervention and control groups exhibited changes in hair loss symptoms over time. This suggests that hair loss symptoms varied throughout the study, regardless of group assignment. Additionally, the group factor did not show significant effects ($F(1, 118) = 0.107$, $p = 0.744$, partial $\eta2 = 0.001$), indicating no notable differences in the progression of hair loss symptoms between the intervention and control groups. This implies that the intervention did not noticeably impact hair loss symptoms independent of time. Furthermore, while the interaction between group assignment and time was insignificant, this effect was not statistically significant in this analysis.

Table IV presents a comparison of the mean scores for physical side effects between the intervention and control groups from baseline through the 3rd follow-up. These side effects include nausea, vomiting, diarrhea, constipation, fatigue, hair loss, mouth, gum, and throat infections, as well as skin and nail alterations experienced during chemotherapy. These findings show the significant effect of the intervention across different time points. Initially, no statistically significant differences were observed in mean ratings of Physical effects between the intervention and control groups at baseline. However, at the first follow-up in the intervention group, a significant increase in mean scores compared to the control group was noted for all physical effects except hair loss. Positive significant changes persisted in the 2nd and 3rd follow-ups, with Physical effects of chemotherapy remaining significantly elevated compared to baseline and control group levels ($p<0.05$). In contrast, the control group exhibited a significant decrease in mean scores from the 1st follow-up onwards. Notably, no significant association was found for hair loss, with mean scores increasing from baseline to the 3rd follow-up without substantial differences compared to the control group. Overall, these findings highlight the substantial impact of the intervention on alleviating various physical effects of chemotherapy, with particular emphasis on nausea, while also indicating the need for further investigation regarding the intervention's efficacy concerning hair loss.

Table IV : Comparison of Mean Score Changes in Physical side effects 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)			
Nausea					
Baseline	1.367±0.920	1.467±0.791	0.100 (-0.210, 0.410)	0.638(118)	0.524
1st follow-up	1.100±1.069	1.767±0.767	0.667 (0.330, 1.00)	3.925(118)	<0.001**
2nd follow-up	0.850±0.860	2.05±0.746	1.218 (0.927, 1.509)	8.163(118)	<0.001**
3rd follow-up	0.567±0.722	2.550±0.565	1.983 (1.749, 2.218)	16.758(118)	<0.001**
Vomiting					
Baseline	1.567±0.945	1.400±0.906	-0.167 (-0.501, 0.168))	-0.986(118)	0.326
1st follow-up	1.367±0.974	1.783±0.783	0.417 (0.097, 0.736))	2.583(118)	0.011*
2nd follow-up	1.067±1.006	2.200±0.732	1.133 (0.815, 1.452)	7.056(118)	<0.001**
3rd follow-up	0.733±0.861	2.467±0.596	1.733 (0.479,1.198)	12.825(118)	<0.001**
Diarheaa					
Baseline	2.067±0.548	2.133±0.676	0.067 (-0.156, 0.289)	0.593(118)	0.554
1st follow-up	2.683±0.567	1.917±0.619	0.717 (0.500, 0.934)	6.539(118)	<0.001**
2nd follow-up	1.400±0.669	2.683±0.669	1.283 (1.059, 1.508)	11.334(118)	<0.001**
3rd follow-up	1.000±0.664	2.733±0.482	1.733 (1.524, 1.943)	16.361(118)	<0.001**
Constipation					
Baseline	2.083±0.850	1.817±1.097	-0.267 (-0.621, 0.088)	-1.489(118)	0.139
1st follow-up	1.783±0.715	2.300±1.253	0.517 (0.148, 0.885)	2.774(118)	0.006
2nd follow-up	1.283±0.885	2.400±1.196	1.117 (0.736, 1.497)	5.814(118)	<0.001
3rd follow-up	0.667±0.914	2.400±1.138	1.733 (1.360, 2.107)	9.197(118)	<0.001

CONTINUE

Outcome measures	Mean ± SD		Mean difference (95%CI)	T statistic (df)	p-value
	Intervention group (n =60)	Control group (n= 60)			
Fatigue					
Baseline	1.417±0.696	1.483±0.537	0.067 (-0.158, 0.261)	0.588(118)	0.558
1st follow-up	1.000±0.759	1.600±0.527	0.600 (0.364, 0.836)	5.028(118)	<0.001**
2nd follow-up	0.800±0.732	1.733±0.634	0.933 (0.686, 1.181)	7.465(118)	<0.001**
3rd follow-up	0.550±0.594	1.850±0.633	1.300 (1.078, 1.522)	11.595(118)	<0.001**
Hair loss					
Baseline	2.333±0.655	2.400±0.643	0.067 (-0.168, 0.301)	0.562(118)	0.575
1st follow-up	2.467±0.873	2.450±0.649	-0.167 (-0.297, 0.261)	-0.119(118)	0.906
2nd follow-up	2.617±1.010	2.517±0.596	-0.100 (-0.400, 0.200)	-0.660(118)	0.510
3rd follow-up	2.667±1.052	2.550±0.565	-0.117 (-0.422, 0.189)	-0.757(118)	0.451
Mouth gum throat infection					
Baseline	1.117±0.524	1.517±0.725	0.033 (-0.206, 0.273)	0.276(118)	0.783
1st follow-up	1.083±0.497	1.600±0.807	0.400 (0.171, 0.629)	3.465(118)	0.001*
2nd follow-up	1.083±0.497	1.600±0.807	0.517 (0.274, 0.759)	4.223(118)	<0.001**
3rd follow-up	0.967±0.581	1.667±0.837	0.700 (0.439, 0.961)	5.321(118)	<0.001**
Skin nail changes					
Baseline	1.250±0.950	1.183±0.813	-0.067 (-0.386, 0.253)	-0.413(118)	0.680
1st follow-up	1.167±0.994	1.267±0.756	0.100 (-0.219, 0.419)	0.620(118)	0.536
2nd follow-up	0.967±0.863	1.317±0.725	0.350 (0.062, 0.638)	2.406(118)	0.018
3rd follow-up	0.667±0.752	1.450±0.675	0.783 (0.525, 1.042)	6.008(118)	<0.001

*** p < 0.05, ** p < 0.001**

DISCUSSION

In the present study, we investigated the impact of a newly developed counselling module with repetitive counselling by the pharmacist on the physical side effects of breast cancer receiving chemotherapy. We determined this impact by applying the CTCAE questionnaire. There was no statistically significant difference found between the intervention group and the control group, in attributes, they were deemed similar in this regard.

i) Nausea and Vomiting

According to the mean scores for nausea and vomiting, significant reductions ($p < 0.05$) were seen in intervention groups; however, increased mean scores were observed in the control group. The significant decrease observed in the mean scores of nausea and vomiting suggests that the intervention counselling module did have a significant impact among breast cancer patients. Consistent with these findings, where patients undergoing chemotherapy experienced nausea and vomiting as side effects and expressed that these symptoms had an adverse influence on their overall quality of life. Pharmacists, as experts in medications, added significant value to the management of patients' conditions where a measurable reduction can be observed in nausea and/or vomiting in chemotherapy cancer patients (10).

ii) Diarrhea

The seriousness of chemotherapy-induced diarrhea (CID) can lead to a reduced quality of life and negatively affect cancer treatment outcomes. This study showed a significant interaction between group and time concerning diarrhea and follow-up counselling. Pharmacists can play a vital role in recognizing patients susceptible to chemotherapy-induced diarrhea (CID) and initiating timely interventions (11). Statistical significant improvement was observed between managing constipation and repetitive chemotherapy counseling among breast cancer patients in the intervention group over time.

iii) Constipation

Constipation is a common challenge among individuals undergoing cancer treatment, affecting approximately 60% of patients overall (12). This study echoes this prevalence, with 67.5% of participants experiencing chemotherapy-induced constipation. Notably, there was a significant correlation between managing constipation and receiving repetitive chemotherapy counseling among breast cancer patients in the intervention group over time. The average constipation score consistently decreased throughout the follow-up counselling sessions compared to the control group, with particularly significant improvements noted at the third follow-up. A separate study enhanced patient symptom management through a collaborative drug therapy management (CDTM) program led by pharmacists (13). This initiative empowered pharmacists to independently manage gastrointestinal issues in cancer patients, such as diarrhea and constipation, leading to notable symptom improvements. Additionally, pharmacist interventions led to enhanced symptom control, better medication adherence, and overall improved patient outcomes (13). Furthermore, these findings align with another educational intervention conducted to evaluate whether pharmacist-led education enhances the documentation of bowel function assessments among cancer patients using opioids by healthcare staff (14). The study concluded that pharmacist-led educational initiatives significantly improved the documentation of bowel function assessments performed by clinical staff for adult cancer patients, thus highlighting the importance of pharmacist involvement in optimizing patient care (14).

iv) Fatigue

The intervention group showed a reduction in the average level of fatigue-related physical effects compared to the control group, which received repetitive counseling from pharmacists. Patients should receive educational programs focusing on the causes and management of fatigue to enhance their ability to cope and implement effective management techniques (15). Additionally, research by Waart (16) demonstrated that integrating mild home-based physical activity and moderate to high-intensity aerobic exercise significantly preserved patients' physical fitness, reduced fatigue, and enhanced their overall quality of life compared to standard care. Following these findings, a study conducted by Animaw et al. (15) identified various factors significantly correlated with cancer-related fatigue (CRF), including anemia, physical inactivity, specific cancer treatments (such as a combination of surgery and chemotherapy), treatment cycle, and undernutrition. These findings underscore the importance of early fatigue screening by healthcare providers and the subsequent implementation of tailored management strategies. Additionally, there is a clear need for educational programs to elucidate the etiology and treatment options for fatigue among cancer patients. By equipping patients with coping strategies and management techniques, such programs can significantly enhance their ability to navigate and mitigate the impact of cancer related fatigue (15).

v) Hairloss

Chemotherapy-induced alopecia (CIA) is a distressing side effect for cancer patients undergoing systemic cytotoxic treatment, significantly impacting their quality of life. Despite the emotional toll it takes, effective remedies for the CIA remain elusive. Research by Freites-Martinez et al. (17) and Saraswat et al. (18) highlights the widespread fear and concern associated with hair loss among chemotherapy patients. However, our study found no significant changes in hair loss severity over time, with the intervention group showing

no improvement compared to the control group. Studies by Tanaka et al. (19) and Rubio-Gonzalez et al. (20) echo the prevalence of CIA and its detrimental effects on patients' well-being. Despite the reversible nature of chemotherapy-induced hair loss, managing the condition remains a challenge, as emphasized in our study. Although pharmacists' counseling sessions primarily focused on managing existing hair loss and promoting gentle hair care, the severity of hair loss persisted unchanged in both intervention and control groups. While counseling sessions play a crucial role in addressing patients' concerns, further research is needed to explore effective strategies for preventing hair loss and promoting regrowth. Bhoyrul et al. (21) emphasize the need for advancements in this area to alleviate the emotional burden of CIA and enhance treatment compliance. Such developments hold the potential to significantly improve the quality of life for cancer patients undergoing chemotherapy, ultimately contributing to better treatment outcomes.

vi) Mouth, Gum, and Throat Infection

The mean score of mouth, gum, and throat infection decreased over time in intervention patients compared to the control group. While no significant difference was observed between the intervention and control groups during the initial and subsequent follow-ups, a notable association emerged during the third follow-up as time progressed. The effectiveness of pharmacist interventions in reducing the occurrence of adverse effects of chemotherapy treatment is supported by findings from studies such as that by Iihara et al. (22). Their research highlights the importance of aligning medical interventions targeting non-hematological adverse events with recommendations provided by pharmacists. Additionally, Barkokebas et al. (23) conducted a cross-sectional study assessing oral health in cancer patients undergoing radiotherapy or chemotherapy. Their findings underscore the significant impact of cancer treatment on oral quality of life, further emphasizing the importance of comprehensive care approaches in oncology.

vii) Nails and skin changes

Alteration of the nails and skin is a recognized adverse effect of systemic chemotherapy. In this study, no significant effect was observed during the initial follow-up, and subsequent assessments revealed a notable association, with the mean score decreasing in the intervention group compared to the control group. Furthermore, Zawar's study (24) involving 129 patients underscored the prevalence of nail changes, observed in 71.3% of individuals, emphasizing the importance of educating patients about potential side effects associated with chemotherapy drugs. Studies emphasize the importance of improving clinicians' knowledge of chemotherapy-induced nail changes. This knowledge enables healthcare providers to offer proactive counseling to patients and caregivers about the likelihood of experiencing nail changes during and after chemotherapy treatment. Such counseling efforts can enhance patient adherence and optimize the duration of chemotherapy administration, potentially leading to improved treatment response rates (25, 26)

The significance of pharmacists in counseling breast cancer patients undergoing chemotherapy

Our research demonstrates the efficacy of a newly developed intervention module for breast cancer patients undergoing chemotherapy, particularly in mitigating physical side effects through repetitive counseling. This underscores the critical role of pharmacists in delivering comprehensive care to cancer patients. Pharmacists, equipped with expertise in pharmacological and non-pharmacological management of common side effects, are pivotal in providing information about chemotherapy regimens and potential side effects to patients undergoing cancer treatment (27).

Consistent with prior research, our findings suggest that ongoing counseling, support, and patient care contribute to improved mental and physical recovery. Pharmacists serve as valuable collaborators within the multidisciplinary oncology care team, working alongside surgeons, oncologists, and primary care providers to optimize drug therapy and promote adherence to chemotherapy. Studies have shown that guidance from pharmacists regarding adverse events, coupled with personalized prescriptions tailored to manage these events, positively impacts the treatment environment and enhances patients' quality of life (18). In line with these insights, our study reveals that continuous counseling provided by pharmacists resulted in a reduction of physical side effects among cancer patients undergoing chemotherapy. Introducing repetitive counseling sessions at the onset of systemic therapy led to improvements in quality of life. Therefore, we recommend implementing repetitive counseling sessions by pharmacists during cancer patients' treatment to effectively alleviate the physical effects due to chemotherapy, both during and after the treatment period (28).

Strengths and Limitations of the Study

The findings of this study offer valuable insights that can aid future researchers in accurately identifying the unique needs of cancer patients undergoing chemotherapy. They underscore the importance for healthcare professionals to remain mindful of factors that may impact these patients. However, a limitation of this study is that the patient samples were exclusively drawn from a single center, which may restrict the generalizability of the findings. Despite this constraint, the study's findings significantly highlight the importance of counseling for breast cancer patients undergoing chemotherapy. The results illustrate the value of implementing counseling interventions to consistently monitor and mitigate physical side effects throughout the treatment process.

CONCLUSION

In conclusion, pharmacists play a vital role within the cancer care team, serving as an indispensable component that contributes to the broadening and enhancement of patient care. The chemotherapy counseling module developed for pharmacists, along with repetitive counseling sessions, proved to be effective among breast cancer patients undergoing chemotherapy. In this current study, the module has demonstrated its efficacy in lessening the physical side effects of chemotherapy among breast cancer patients receiving chemotherapy. Notably, this study marks one of the pioneering efforts in Malaysia, as it evaluates the effectiveness of repetitive chemotherapy counseling 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 quality of life throughout the chemotherapy treatment. Due to that, it is suggested to propose repetitive counseling sessions by pharmacists during the treatment of cancer patients to reduce their physical side effects both during and after the chemotherapy treatment.

Recommendations for implementation of intervention

This module can be proposed for integration into hospital settings, specifically designed for breast cancer patients undergoing chemotherapy to alleviate associated adverse effects. It empowers pharmacists to provide personalized care, addressing the physical challenges induced by chemotherapy. Considering the module's proven efficacy, it could be recommended to the Pharmacy Practice & Development Division at the Ministry of Health Malaysia (KKM) for additional research and wider adoption in clinical settings. Incorporating repetitive counseling sessions at regular intervals throughout treatment cycles ensures continuous monitoring of the module's effectiveness in supporting breast cancer patients. This systematic approach guarantees ongoing assessment and enhancement of patient well-being throughout their treatment journey.

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