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EFFECTIVENESS OF CHEMOTHERAPY COUNSELLING BY PHARMACISTS ON PHYSICAL EFFECTS (NAUSEA AND VOMITING) AMONG ONCOLOGY PATIENTS IN A GOVERNMENT HOSPITAL IN MALAYSIA- A RANDOMISED CONTROLLED TRIAL

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Abstract: Chemotherapy used as drugs alone or a combination plays a major role in the treatment of cancer. The objectives of the study were to develop, implement and evaluate the outcome of a chemotherapy counselling module among oncology patients by pharmacists based on their nausea and vomiting. Methodology: A randomized, single blind, placebo controlled study design was used in this study. A total of 162 patients were randomly selected and allocated into intervention and control groups using a single blind method. Intervention: Counselling module 'Managing Patients on Chemotherapy' along with repetitive counseling for oncology patients undergoing chemotherapy.
Outcome: Effectiveness of counseling module 'Managing Patients on Chemotherapy' Pharmacists during baseline, first follow-up post-intervention, second follow-up and third follow-up. Results: Physical effects showed large effect size for nausea ($p = 0.001$, partial $\eta^2 = 0.434$), and vomiting ($p = 0.001$, partial $\eta^2 = 0.337$). Conclusion: In conclusion, the 'Managing Patients on Chemotherapy' by Pharmacists counselling module has been shown to be effective in improving nausea and vomiting side effects among oncology patients undergoing chemotherapy.
KEY-WORDS: Cancer, chemotherapy, nausea, vomiting, counseling, repetitive, pharmacist

1. Introduction

Cancer needs continuous treatment and requires monitoring in the long term. By definition, cancer refers to the uncontrolled growth and spread of cells. Chemotherapy, used alone or in combination with surgery and or radiotherapy, plays a major role in the treatment of cancer. Chemotherapy drugs affect cell growth and cell division, and they kill both tumour cells and normal cells with similar biological characteristics [1], [2]. Chemotherapy is also known to cause negative physical effects including anorexia, nausea, vomiting, fatigue, constipation, diarrhoea, neuritis and mucosites [3]. Cancer diagnoses have a serious impact on the patient's social and family life. Studies on the side effects of cancer and chemotherapy treatment show that the incidence of suicide is double among those diagnosed with cancer compared to the general population. The prevalence for chemotherapy induced physical effects were 90.9% had nausea and 72.0% had vomiting at initial treatment [4]. It is well known that, cancer patients suffer from chemotherapy treatment side effects. This suffering is usually observed by pharmacists who are in charge of administering chemotherapy to their patients. Therefore pharmacists also need to play a role in helping these patients cope and /or overcome side effects of chemotherapy. Most common physical effects were selected according to the prevalence studies. These physical effects were nausea and vomiting. This study aims to develop and implement a chemotherapy counselling module among oncology patients by pharmacists.

2. Materials and Method

A. Study design and site

A randomized controlled trial (RCT) was carried out between July 2013 and February 2014 at a government hospital in Malaysia. All patient aged above 18 years was approached prior data collection and informed consent was obtained. This represents the age of adulthood as defined by World Health Organization [5]. All cancer patients in stage I,II, III and IV undergoing their first and second chemotherapy cycle treatments were included in the study.

Participants from both intervention and control groups were single blinded. Based on the patient's current appointments for their upcoming cycle, the intervention group had a baseline evaluation and three consecutive follow-ups. Only patients with cancer undergoing their first and second cycle of chemotherapy and who were Malaysian citizens were included in the study so as to standardize patients' severity of side–effects caused by chemotherapy. Patients with severe communication problems including speech or hearing impairments and those too ill to participate were also excluded from the study.

B. Development of intervention

Feedback from patients through focus group discussion (FGD), pilot test and combined with the "Chemotherapy and You" module by the National Cancer Institute (NCI) a new counseling module was produced which is the 'Managing Patients on Chemotherapy' by Pharmacists module. This newly developed module covers a wider range of areas; which include:

- Preparations to be done before, during and after chemotherapy
- Nutrition as well as food that is to be consumed and not to be consumed before, during and after chemotherapy.
- Do's and Don'ts before, during and after chemotherapy
- Details of general side-effects suffered by the patients on chemo drugs.
- Measures to reduce and manage side-effects specifically on nausea and vomiting

The module was checked and screened by a panel of experts consisting of consultants and specialists in Pharmacy, Family Medicine, Public Health, Psychology, Oncology, Nutrition and Pharmacology. This new module provides evidence-based information to pharmacists in counseling patients and emphasizes the importance in spending quality time with the patients as they undergo each chemotherapy cycle. Compared to the existing practice where pharmacists provide general explanation on the side effects of chemotherapy drugs to oncology patients based on their own knowledge and experience.

C. Randomization and blinding procedure

A list of all cancer patients who met the inclusion criteria in the selected hospital was used as the sampling frame of the study. A total of 162 patients were recruited for both intervention and control groups; with each group consisting of 81 patients. For recruitment purposes, patients who came for chemotherapy according to their appointment dates and who met the inclusion criteria were given numbers beginning with 1, 2, 3,…and so on until 162 patients were obtained. Odd and even numbers selection was used to randomly assign the selected 162 patients; where the odd numbers were assigned to the intervention group and the even numbers were assigned to the control group. The intervention group received chemotherapy counseling based on the 'Managing Patients on Chemotherapy' by Pharmacists counseling module which was administered by the pharmacist-in-charge of this study.

The patients in the control group received treatment-as-usual (TAU). This consisted of pharmacist explanation based on their own knowledge and this usually only done during the first cycle of chemotherapy. Patients in the intervention group received chemotherapy counseling based on the newly developed module during their baseline, 1st follow-up, 2nd follow-up and 3rd follow-up sessions. Figure 1 shows a flow chart for the data collection procedure in the intervention and control groups. The data collection involved 4 sessions altogether; baseline session, 1st follow-up session, 2nd follow-up session and 3rd follow-up session.

A baseline evaluation was performed on both intervention and control groups using the pretested questionnaires using the Common Terminology Criteria for Adverse Events (CTCAE) 4.0 questionnaire. This evaluation was conducted prior to the implementation of the chemotherapy counseling module in the intervention group. The efficacy endpoints were measured for three consecutive chemotherapy cycles; which were defined as 1st, 2nd and 3rd follow-up sessions in this study. The duration between each cycle ranged from 3- 6 weeks. It took 12 -18 weeks to complete the data collection.

3. Instrument

Socio-demographic characteristics. Items on the socio-demographic characteristics included age, gender, religion, education level, number of family members living together, employment status, marital status, type of cancer, stage of cancer, and family history with cancer

Common Terminology Criteria for Adverse Events (CTCAE) version 4.0. **Assessment of Physical Effects of Chemotherapy**

This section consisted of the Common Terminology Criteria for Adverse Events (CTCAE) version 4.0 questionnaire [6] to determine the physical effects encountered by patients. This section collected information on common side effects encountered by cancer patients which are nausea and vomiting. For every grade on symptoms using the CTCAE guideline, patients were required to mark (x) on the following grade none (0), mild(1), moderate (2), severe (3) and life-threatening (4); depending on the severity of the adverse event due to the chemotherapy treatment.

Table 1: The summary of (Nausea and Vomiting)

Physical effects	**1 (Mild)**	**2 (Moderate)**	**3 (Severe)**	**4 (Life-threatening)**
Nausea	Loss of appetite without alteration in eating habits	Oral intake decreased without significant weight loss, dehydration or malnutrition	Inadequate oral caloric or fluid intake; tube feeding, TPN, or hospitalization indicated	
Definition: A disorder characterized by a queasy sensation and/or the urge to vomit				
Vomiting	1 - 2 episodes (separated by 5 minutes) in 24 hrs	3 - 5 episodes (separated by 5 minutes) in 24 hrs	>=6 episodes (separated by 5 minutes) in 24 hrs; tube feeding, TPN or hospitalization indicated	Life-threatening consequences; urgent intervention indicated
Definition: A disorder characterized by the reflexive act of ejecting the contents of the stomach through the mouth.				

Sample size

The formula by [7] was used for sample size estimation **(**$n_1 = [Z_\alpha \sqrt{pq(1+1/k)} + Z_\beta \sqrt{p_1q_1 + p_2q_2/k}]^2 / \Delta^2$). The prevalence of disease free survival with chemotherapy at 5 years worldwide is 69% [3]. The final sample size was 81 participants in each group.

Ethics Statement

Research ethics approval from the Medical Research Ethics Committee of the participating institution, and also from the National Medical Research Register (NMRR) of Malaysia was obtained prior to data collection. Approval from the Director of the selected hospital was also obtained before commencement of the study.

Statistical analysis

Data were collected and entered manually into the statistical computer software of SPSS version 20 (IBM SPSS Statistics 20, 2011). Data were analyzed using descriptive and inferential statistics. Two- way repeated measures ANOVA test was employed to look at the main and interaction effects within and between groups for mean scores of Nausea and Vomiting. It used partial eta squared (η^2) as a measure of effect size which represents the variance proportion in the dependent variable that can be explained by the independent variable. The interpretation of the strength of eta squared values used the following guidelines by (Cohen, 1988): small effect (0.01), moderate effect (0.06), and large effect (0.14) [8]. Confidence interval was set at 95% for the estimation of odds ratio and mean. The level of significance, alpha (α) was set at 0.05. Analysis on group time comparison were conducted using multiple pair wise comparisons. The level of significance, alpha (α) was set at 0.05 (Bonferroni correction) for these comparisons.

4. RESULTS

Table 2 Socio- demographic characteristics of respondents (N=161)

Characteristics	Frequency, n (%)		Total	p valve (χ^2)
	Intervention group	Control group		
1.Age				
< 45	8(9.9)	13(16.3)	21(26.1)	0.168
45-54	14(17.3)	15(18.8)	29(18.0)	
55-64	21(25.9)	27(33.8)	48(29.8)	
> 64	38(46.9)	25(31.1)	63(39.1)	
Total	81(100)	80(100)	161(100)	t=
Mean, SD	5.11(1.38)	4.84(1.43)	4.98(1.41)	0.219
95%CI	(4.80-5.42)	(4.52-5.16)	(4.76-5.19)	
2.Gender				
Male	34(42.5)	42(52.5)	76(47.2)	0.181
Female	42(52.5)	38(47.5)	85(52.8)	
3.Religion				
Islam	44(54.3)	40(50.0)	84(52.2)	0.527
Buddha	22(27.2)	26(32.5)	48(29.8)	
Hindu	14(17.3)	10(12.5)	24(14.9)	
Christian	1(1.2)	3(3.8)	4(2.5)	
Others	0(0)	1(1.2)	1(0.6)	
No Religion	0(0)	0(0)	0(0)	
4.Marital Status				
Single	8(9.9)	3(3.8)	11(6.9)	
Married	54(66.7)	62(77.5)	116(72.1)	0.306
Widowed	10(12.3)	11(13.7)	21(13.0)	
Divorced	5(6.2)	2(2.5)	7(4.3)	
Separate	4(4.9)	2(2.5)	6(3.7)	
5. Cancer Type				
Breast	30(37.0)	18(22.5)	48(29.8)	
Colorectal	23(28.4)	25(31.2)	48(29.8)	
Cervical	7(8.8)	8(10.0)	15(9.3)	0.516
Ovarian	4(4.9)	3(3.8)	7(4.3)	
Lymphom	4(4.9)	6(7.5)	10(6.3)	
Stomach	6(7.4)	10(12.5)	16(9.9)	
Others	7(8.6)	10(12.5)	17(10.6)	
6. Cancer Stage				
Stage 1				
Stage 2	7(8.6)	9(11.2)	16(9.9)	0.792
Stage 3	16(19.8)	12(15.0)	28(17.4)	
Stage 4	30(37.0)	28(35.0)	58(36.1)	
	28(34.6)	31(38.8)	59(36.6)	

Chi square test (χ^2) *Significant at $p < 0.05$

Table 2 shows the distribution of socio- demographic characteristics of the patients in the intervention and control groups. The results show that there is no significant difference in the proportion of respondents in both groups. The intervention and control groups were compared on socio- demographic characteristics, and physical effects (nausea and vomiting). The comparison was done to ensure that the randomization process in the study was able to generate two groups that were comparable.

Table 3: Baseline comparison on mean scores of Nausea and Vomiting due to chemotherapy treatment for cancer patients between the intervention and control group

Outcome measures	Mean score(SD)			p-value
	Overall	Intervention	Control	
Nausea	1.18(1.10)	1.21(1.11)	1.15(1.09)	0.731
Vomiting	1.45(1.10)	1.48(1.12)	1.41(1.08)	0.692

p value was calculated using an independent t-test
*Significant at p <0.05

Table 4: Baseline comparison on Nausea and Vomiting due to chemotherapy treatment for cancer patients between the intervention and control group

Outcome measures	Frequency, n (%)		Total	p[a] value
	Intervention group	Control Group		
Nausea				
None	28(34.6)	30(37.5)	58(36.0)	
Mild	23(28.4)	20(25.0)	43(26.7)	0.885
Moderate	18(22.2)	18(22.5)	36(22.4)	
Severe	12(14.8)	12(15.0)	24(14.9)	
Vomiting				
None	19(23.5)	20(25.0)	39(24.2)	
Mild	23(28.4)	23(28.8)	46(28.6)	0.984
Moderate	22(27.1)	22(27.5)	44(27.3)	
Severe	15(18.5)	14(17.5)	29(18.0)	
Life-Threatening	2(2.5)	1(1.2)	3(1.9)	

Chi square test (χ^2) *Significant at p <0.05

Evaluation of the effectiveness of the intervention on Nausea and Vomiting

Nausea

The main effect of group, time and group x time interaction on physical effects: Nausea

Table 5 shows the group main effect on nausea means scores from baseline to end of the third follow-up. There was no significant difference in mean scores of nausea between the intervention (mean 1.21, SD =1.11, 95% CI = 0.96 – 1.46) and control (mean =1.15, SD = 1.09, 95%CI = 0.91-1.39) group at baseline (F (1, 160) = 0.118, p = 0.731). However, the mean nausea physical effects scores was significantly different in the intervention than in the control groups first follow up (F (1, 160) = 7.565, p = 0.007), second follow-up (F (1, 160) = 19.787, p = 0.001) and third follow-up (F (1, 160) = 66.066, p = 0.001).

Table 5 Group main effect on Nausea at baseline, 1st follow-up, 2nd follow-up and 3rd follow-up

Outcome measures	Mean ± SD (95%CI)		F (One way Anova)	p value
	Intervention group (n =81)	Control group (n= 80)		
Baseline	1.21 ± 1.11 (0.96-1.46)	1.15 ± 1.09 (0.91-1.39)	0.015	0.731
1st follow-up	1.09 ± 1.09 (0.85-1.33)	1.58± 1.17 (1.32-1.83)	7.565	0.007*
2nd follow-up	0.96± 0.99 (0.74-1.18)	1.70 ± 1.11 (1.45-1.95)	19.787	0.001*
3rd follow-up	0.80± 0.93 (0.60-1.01)	2.01± 0.96 (1.80-2.23)	66.066	0.001*

Table 6: Summary table of two way repeated measures ANOVA for Nausea

Source	Type III Sum of Squares	df	Mean square	F	p value	Partial η^2
Nausea						
Group	56.793	1	56.793	13.496	0.001*	0.078
Error(Between)	669.095	159	4.208			
Time	4.393	2.640	1.664	15.875	0.001*	0.091
Group* Time	33.753	2.640	12.786	121.976	0.001*	0.434
Error within	43.998	419.733	0.105			

*Significant at p<0.

Table 6 shows the results of two way repeated measures ANOVA analysis for nausea on the (intervention and control) and time (baseline, first follow-up, second follow-up, and third follow-up) effects and interaction between group and time. The assumption of sphericity was violated (Mauchly's test (χ^2) = 42.030, p = 0. 0001) and Greenhouse-Geisser corrected estimates were used in the results interpretation. There were significant main effects for group (F (1,159) = 13.496, p = 0.001, partial η^2 = 0.078); time (F (1,159) = 15.875, p = 0.001, partial η^2 = 0.091); and interaction between group and time (F (1,159) = 121.976, p = 0.001, partial η^2 = 0.434). The interaction between group and time is plotted in the graph shown in Figure 1, where nausea severity increased in the control group, but decreased in the intervention group with each counseling session.

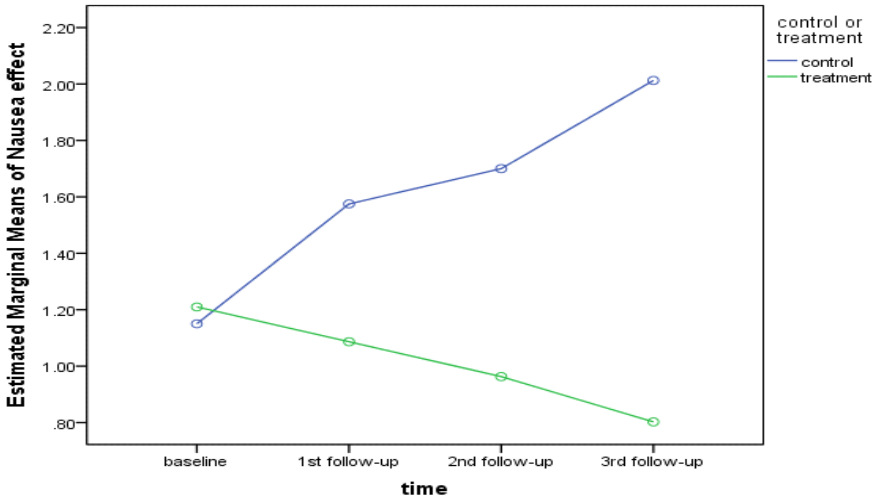

Figure 2 The interaction plot between group and time for means of Nausea

Table 7 and 8 show multiple pairwise comparisons involving group-time comparisons. The level of significance, alpha (α) was set at 0.05 (Bonferroni correction) for these comparisons. The mean differences of nausea effect scores were highly significant for Pair 1(p = 0.007), Pair 2 (p = 0.001), Pair 3 (p= 0.001), Pair 4 (p= 0.007), Pair 5 (p = 0.001) and Pair 6 (p=0.001) for the intervention group as shown in Table 7. In the control group, the mean differences of nausea effect scores were highly significant for Pair 1(p = 0.007), Pair 2 (p = 0.001), Pair 3 (p= 0.001), Pair 4 (p= 0.007), Pair 5 (p = 0.001) and Pair 6 (p=0.001) as shown in Table 8.

Table 7: Multiple pair wise comparisons of Nausea for the intervention group

Group – time comparison Pairs	Mean difference	95% CI for mean difference	p value
Pair 1: Baseline vs 1st follow-up	0.123	0.024 - 0.223	0.007*
Pair 2: Baseline vs 2nd follow-up	0.247	0.116 - 0.377	0.001*
Pair 3: Baseline vs 3rd follow-up	0.407	0.259 – 0.556	0.001*
Pair 4:1st follow-up vs 2nd follow-up	0.123	0.024 – 0.223	0.007*
Pair 5:1st follow-up vs 3rd follow-up	0.284	0.148 – 0.420	0.001*
Pair 6: 2nd follow-up vs 3rd follow-up	0.160	0.049 – 0.272	0.001*

Table 8: Multiple pair wise comparisons of Nausea for the control group

Group – time comparison Pairs	Mean difference	95% CI for mean difference	p value
Pair 1:Baseline vs 1st follow-up	-0.425	-0.576 – (-0.274)	0.001*
Pair 2:Baseline vs 2nd follow-up	-0.550	-0.701 – (-0.399)	0.001*
Pair 3: Baseline vs 3rd follow-up	-0.863	-0.978 – (-0.747)	0.001*
Pair 4:1st follow-up vs 2nd follow-up	-0.125	-0.226 – (-0.024)	0.007*
Pair 5:1st follow-up vs 3rd follow-up	-0.438	-0.589 – (-0.286)	0.001*
Pair 6: 2nd follow-up vs 3rd follow-up	-0.313	-0.454 – (-0.171)	0.001*

Adjustment for multiple comparisons using Bonferroni test *Significant at $p < 0.05$

From the analysis, it is concluded that 'Managing Patients on Chemotherapy' by Pharmacists module and repetitive counselling was effective to overcome nausea side-effects caused by chemotherapy at first follow-up, second follow-up and third follow up with a large effect size $(I)^2 = 0.434$). The large effect size indicates the implementation of the intervention would detect an improvement to overcome nausea effect due to chemotherapy among oncology patients by a large magnitude of difference.

5. Vomiting

The main effect of group, time and group x time interaction on physical effects: Vomiting

Table 9 shows the group main effect on vomiting means scores from baseline to end of the third follow-up. There was no significant difference in mean scores of vomiting between the intervention (mean 1.48, SD =1.12, 95% CI = 1.23 – 1.73) and control (mean =1.41, SD = 1.09, 95%CI = 1.17-1.65) group at baseline ($F(1, 160) = 0.157$, $p = 0.692$). However, the mean vomiting physical effects scores was significantly different in the intervention than in the

control group first follow up (F (1, 160) = 1.973, p = 0.162), second follow-up (F (1, 160) = 5.874, p = 0.016) and third follow-up (F (1, 160) = 33.123, p = 0.001).

Table 10 shows the results of two way repeated measures ANOVA analysis for vomiting on the (intervention and control) and time (baseline, first follow-up, second follow-up, and third follow-up) effects and interaction between group and time. The assumption of sphericity was violated (Mauchly's test (χ^2) = 71.043, p = 0. 001) and Greenhouse-Geisser corrected estimates were used in the results interpretation. There were significant main effects for group (F (1,159) = 5.133, p = 0.025, partial η^2 = 0.031); time (F (1,159) = 15.588, p = 0.001, partial η^2 = 0.089); and interaction between group and time (F (1,159) = 80.833, p = 0.001, partial η^2 = 0.337). The interaction between group and time is plotted in the graph shown in Figure 2, where vomiting severity increased in the control group, but decreased in the intervention group with each counseling session.

Table 9: Group main effect on Vomiting at baseline, 1st follow-up, 2nd follow-up and 3rd follow-up

Outcome measures	Mean ± SD (95%CI)		F One way ANOVA	p value
	Intervention group (n =81)	Control group (n= 80)		
Baseline	1.48 ± 1.12 (1.23-1.73)	1.41 ± 1.09 (1.17-1.65)	0.157	0.692
1st follow-up	1.28 ± 1.09 (1.04-1.52)	1.53± 1.09 (1.28-1.77)	1.973	0.162
2nd follow-up	1.22± 1.05 (0.99-1.45)	1.63 ± 1.06 (1.39-1.86)	5.874	0.016*
3rd follow-up	0.80 ± 0.93 (0.60-1.01)	1.70 ± 1.05 (1.47-1.93)	33.123	0.001*

*Significant at p<0.05

Table 10: Summary table of two way repeated measures ANOVA for Vomiting

Source	Type III Sum of Squares	df	Mean square	F	p value	Partial η^2
Vomiting						
Group	21.814	1	21.814	5.133	0.025*	0.031
Error(Between)	675.730	159	4.250			
Time	3.793	2.466	1.538	15.58	0.001*	0.089
Group*Time	19.669	2.466	7.794	80.83	0.001*	0.337
Error within	38.688	392.07	0.099			

*Significant at p<0.05

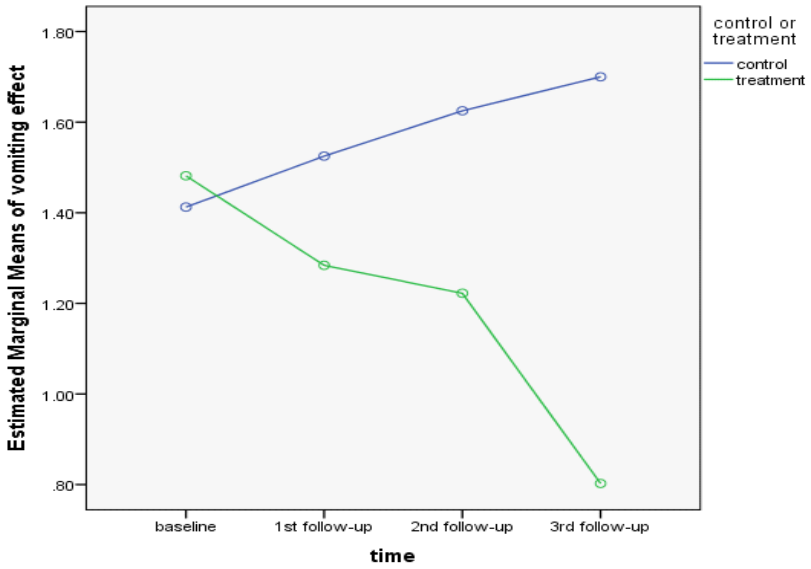

Figure 2 The interaction plot between group and time for means of Vomiting

Table 11 and 12 show multiple pairwise comparisons involving group-time comparisons. The level of significance, alpha (α) was set at 0.05 (Bonferroni correction) for these comparisons. The mean differences of vomiting effect scores were highly significant for Pair 1 (p = 0.001), Pair 2 (p = 0.001), Pair 3 (p= 0.001), Pair 5 (p = 0.001) and Pair 6 (p=0.001) for the intervention group except for Pair 4 (p= 0.146) which was not significant as shown in Table 11. In the control group, the mean differences of vomiting effect scores were significant for Pair 1 (p = 0.013), Pair 2 (p = 0.001), Pair 3 (p= 0.001), Pair 4 (p= 0.024), Pair 5 (p = 0.001) and Pair 6 (p=0.080) as shown in Table 12.

Table 11: Multiple pair wise comparisons of Vomiting for the intervention group

Group – time comparison Pairs	Mean difference	95% CI for mean difference	p value
Pair 1:Baseline vs 1st follow-up	0.198	0.077- 0.318	0.001*
Pair 2:Baseline vs 2nd follow-up	0.259	0.127 - 0.392	0.001*
Pair 3: Baseline vs 3rd follow-up	0.679	0.530 – 0.828	0.001*
Pair 4: 1st follow-up vs 2nd follow-up	0.062	-0.011 – 0.135	0.146
Pair 5: 1st follow-up vs 3rd follow-up	0.481	0.330 – 0.633	0.001*
Pair 6: 2nd follow-up vs 3rd follow-up	0.420	0.270 – 0.569	0.001*

Adjustment for multiple comparisons using Bonferroni test *Significant at $p < 0.05$

Table 12: Multiple pair wise comparisons of Vomiting for the control group

Group – time comparison Pairs	Mean difference	95% CI formean difference	p value
Pair 1: Baseline vs 1st follow-up	-0.112	-0.209 – (-0.016)	0.013*
Pair 2: Baseline vs 2nd follow-up	-0.212	-0.337 – (-0.088)	0.001*
Pair 3: Baseline vs 3rd follow-up	-0.287	-0.425 – (-0.150)	0.001*
Pair 4: 1st follow-up vs 2nd follow-up	-0.100	-0.191– (-0.009)	0.024*
Pair 5: 1st follow-up vs 3rd follow-up	-0.175	-0.291 – (-0.059)	0.001*
Pair 6: 2nd follow-up vs 3rd follow-up	-0.075	-0.155 – (-0.005)	0.080

Adjustment for multiple comparisons using Bonferroni test *Significant at $p < 0.05$

From the analysis, it is concluded that 'Managing Patients on Chemotherapy' by Pharmacists module and repetitive counselling was effective to overcome vomiting side-effects caused by chemotherapy at first follow-up, second follow-up and third follow up with a large effect size ($\Pi^2 = 0.337$). The large effect size indicates the implementation of the intervention would detect an improvement to overcome vomiting effect due to chemotherapy among oncology patients by a large magnitude of difference.

6. DISSCUSION

The present study showed that the attrition rate at the end of the third chemotherapy follow-up was low (0.62%). It has been reported that an attrition rate of between 5% and 20 % would influence the conclusions of the study and subjected to the possibilities of bias [9]. Survivors of cancer are likely to experience adverse psychosocial and physical effects of the disease and its treatment. The present study is considered to be the first study in Malaysia which works on evaluating the effectiveness of repetitive chemotherapy counselling by pharmacists. A study conducted locally on the critical side effects linked to chemotherapy for cancer treatment use found that every individual suffers from different side-effects according to the chemotherapy or medication used. This makes it obligatory for clinicians to stay in touch with cancer patients receiving chemotherapy so as to palliate or prevent any side effects that occur [10].

This study was able to determine the percentage of patients who had chemotherapy induced physical effects using a structured questionnaire. CTCAE 4.0 system classified the grade of physical effects on a scale from one (mild) to five (death). In this study, for nausea and vomiting, there were no significant differences between the intervention and control group at the baseline. Results showed that at baseline 64.0% had nausea and 75.8% had vomiting. A similar study revealed that 90.9% had nausea and 72.0% had vomiting at initial treatment [4]. However there was significant improvement with large effect size for nausea and vomiting upon repetitive chemotherapy counseling among oncology patients in the intervention group. In comparison to the control group there were significant reductions in the severity of nausea and vomiting in the intervention group upon the subsequent follow-ups. A study supported this finding, where it demonstrated the added value when clinical pharmacists were directly

involved in cancer patients' care as the drug experts [11]. The need for the pharmacist involvement grew significantly with the shift from a disease-centered to a patient-centered care. With that shift, a patient's quality of life became a measure that is, perhaps as important as the disease progression [12].

7. Strengths and Limitations

The major strength of the study was the use of a randomized, single blind, placebo controlled study design to evaluate the effectiveness of the chemotherapy counseling module focusing on QOL. The study design measured the efficacy of an intervention on the outcome measures. To assist in controlling the effect of history, a pre test for baseline assessment prior to the intervention, as well as administering a post-test evaluation was conducted. This test controlled the events that happened outside the experiment which could have affected the measurement of the outcomes. The limitation in the study was that, there were no other local publications or studies found in this area. As far as we know this is the first study conducted in Malaysia on improving physical effects due to chemotherapy side effects.

8. Conclusion

In conclusion, chemotherapy counseling module developed for pharmacist together with repetitive counseling was effective among oncology patients receiving chemotherapy in improving patient's physical effects. In the present study the 'Managing Patients on Chemotherapy' by Pharmacists module has been shown to be effective in improving nausea and vomiting among oncology patients undergoing chemotherapy.

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