Effectiveness of a developed module for colorectal cancer patients receiving chemotherapy in reducing depression at the National Cancer Institute, Malaysia

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ABSTRACT

Introduction: Colorectal cancer (CRC) is one of the most common cancers globally. The burden continues to grow globally, exerting tremendous physical, emotional and financial strain on individuals, families, communities and health systems.CRC patients undergoing chemotherapy frequently experience considerable depression. The objective of the study was to develop, implement, and evaluate the effectiveness of the developed module for pharmacists in reducing depression among CRC patients undergoing chemotherapy.

Materials and methods: A systematic, single-blinded study involving 98 patients receiving chemotherapy was carried out at the National Cancer Institute (NCI). The estimated sample size was 98 participants (49 in each group). A self-administered validated questionnaire was used to collect data on the sociodemographic characteristics of the respondents. The validated PHQ-9 (Patient Health Questionnaire-9) and the Multidimensional Scale of Perceived Social Support (MSPSS) were used to assess the depression level and social support of the patients. The intervention group received chemotherapy counselling using the newly developed module during their first, second, and third follow-up. The control group received the standard practice chemotherapy counselling upon their initial visit and during the first cycle. Data were analysed using the Statistical Package for Social Sciences (SPSS) version 26. Independent t-test and two-way repeated measures analysis of variance (ANOVA) were used to analyse the effectiveness of the intervention. A p-value <0.05 was considered significant, and partial eta squared was used to measure effect size.

Results: All participants completed the questionnaire at baseline and followed the first, second, and third chemotherapy counselling sessions, giving a response rate of 100%. No significant difference was detected between the intervention and control groups at the baseline concerning sociodemographic characteristics, depression and social support. The depression scores of the intervention group recorded significant decrements at the third follow-up (p= 0.043), indicating the effectiveness of repetitive counselling in addressing the psychological issues faced by CRC patients.

Conclusion: The newly developed counselling module was effective in reducing depression among colorectal cancer patients undergoing chemotherapy. This study provided evidence-based data on repetitive counselling in improving the psychological and social support of chemotherapy in CRC patients by pharmacists.

KEYWORDS:
Colorectal Cancer; Chemotherapy; Counselling; Depression

INTRODUCTION

Cancer was the second most frequent cause of mortality in 2018, with lung (2.09 million cases), breast (2.09 million cases), and colorectal (1.80 million cases) cancers being the top three.[1] World Health Organization (WHO) also reported stomach (783,000 deaths), colorectal (862,000 deaths), and lung (1.76 million deaths) cancers as the most frequent causes of mortality.[1]

Cancer represents several illnesses that can affect any body part. The disease also encompasses dangerous tumours and neoplasms. Cancer is characterised by the uncontrolled development of unusual cells beyond their boundaries. The cells might attack abutting body parts and spread to other organs, a phenomenon termed metastasis. Cancer mortalities are primarily due to metastases.[1]

Cancer patients frequently suffer from depression.[2] Colorectal cancer (CRC) patients are particularly susceptible to depression. Naser et al.(2021) reported that depression was commonly documented by CRC patients receiving chemotherapy.[3] Depressed cancer patients exhibit poor compliance towards medication, exacerbating their condition.[3]

CRC begins in the colon or rectum and is the second most common cancer in Malaysia, documenting 14.1% of the cancer cases in the nation.[4] In chemotherapy, medications are applied to kill cancer cells. Nevertheless, the medications have potential side effects, including physical (nausea, vomiting, anorexia, diarrhoea, constipation, anaemia, hair loss, and skin and nail changes) and psychological effects (depression).[5]

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Individuals suffering from depression exhibit sadness, inadequate interest or enjoyment of life, feeling guilty, low self-esteem, sleeplessness, trouble eating, fatigue, and difficulty concentrating. The disorder can persist or recur, considerably affecting the capacity of the day-to-day functions of patients. Depression is the most prevalent mental disorder linked to suicide which is related to cancer.6

MATERIALS AND METHODS

Study Design and Setting

The current study was a single-blind design involving cancer patients 18 years old or above, undergoing chemotherapy at NCI, who were able to communicate verbally. The participants were unaware of which treatment group they were in, but the researcher was aware of the treatment groups. Participants with language barriers and severe illnesses were excluded from this study. Sample size was calculated using a power of 90%, response rate of 80% and p of 0.05. Hence, the required sample size was 98.The 98 participants selected were systematically divided into the intervention and control groups. Participants in the intervention group were provided with chemotherapy counselling according to the newly developed module by the investigator. Meanwhile, the control group was provided with standard practice chemotherapy counselling to manage side effects. The intervention group received continuous chemotherapy counselling from their first through to their third follow-up, whereas the control group only received counselling upon their initial visit and during the first cycle.
In this study, the data obtained were analysed with SPSS version 26. Independent t-tests were also employed to compare the variables at baseline. The effectiveness of the intervention was determined with two-way repeated-measure ANOVA assessments. Accordingly, p-values under 0.05 were deemed notable, while partial eta squared represented the effect size.

Sampling Technique

The patients with chemotherapy appointments who met the pre-determined criteria were assigned numbers 1 to 98. The participants with odd numbers were included in the intervention group, while the control group had patients with even numbers. The participants of the intervention group underwent chemotherapy counselling from the investigator, followed by a specific module provided by pharmacists. Meanwhile, the patients in the control group maintained their regular treatment at NCI.

Intervention Module

The newly developed intervention module combines elements of Depression and Social Support. The final iteration of the module was finalized after a pilot study conducted with colorectal cancer patients undergoing chemotherapy, followed by an evaluation by a panel of experts. The module presents an overview of topics associated with colorectal cancer and its chemotherapy treatment. Chapter One introduces colorectal cancer, detailing its risk factors, stages, and treatment options, including chemotherapy. Chapter Two examines chemotherapy drugs and their possible side effects, as well as the preparations needed before, during, and after chemotherapy. Chapter Three addresses the management of physical side effects from chemotherapy, while Chapter Four explores coping strategies for dealing with emotions such as depression. The primary objective of this module is to reduce depression levels experienced by CRC patients. The intervention involved repetitive counselling by pharmacists after every chemotherapy cycle for those in the treatment group. Each counselling session lasted around 60 minutes per patient. These sessions were conducted face-to-face and in person by pharmacists. In contrast, patients in the control group were provided counselling through the hospital's standard counselling practices.

Questionnaire

The current study employed a pre-tested and validated questionnaire in English and Bahasa Malaysia. The survey consisted of three parts: sociodemographic profile, patient health questionnaires (PHQ-9) for depression, and social support multidimensional scaleaofaperceivedasocial support (MSPSS) for social support. In the sociodemographic section, the age, gender, race, marital status, education level, cancer profile (such as cancer stage, number of treatment cycles), and whether the patients were worried about the side effects of the chemotherapy were inquired.

Data Analysis

Descriptive and inferential statistical analyses were performed with SPSS version 26 (IBM SPSS Statistics 26, 2019). Subsequently, the sociodemographic characteristics of the participants were described according to the frequency, mean, standard deviation and percentage. The chi-square test was also adopted to determine the homogeneity of the sociodemographic variables of the patients in the intervention and control groups. Nevertheless, Fisher's exact test was applied when the number of expected counts of a category was under five for a 2 × 2 table.

The baseline data of the intervention and control patients were compared with an independent t-test. Meanwhile, non-normally distributed data were subjected to the Mann-Whitney U test. The effectiveness of the intervention implemented in this study was determined through the general linear model (GLM) with repeated-measure ANOVA. Subsequently, multiple pairwise comparisons were conducted within groups according to a pre-determined significance level of 0.05 alpha (α) value (Bonferroni correction). Furthermore, pairwise comparison effects between intervention and control groups over time were established by utilising independent t-tests. The level of significance, p-value, for the evaluations was set at 0.05.

Ethical Approval

This study procured ethical clearance from the National Medical Research Registry (NMRR) (NMRR ID-22-00402-1V0 (IIR) and NCI prior to data collection. The information forms provided to the participants communicated the objectives and data collection process. Written consent was procured from the patients before data collection.

RESULTS

Tables I summarise the baseline sociodemographic characteristics of the intervention and control groups evaluated in the current study. No significant variations were

Table I: The distribution of the patients' sociodemographic characteristics in the intervention and control groups

Characteristic	Frequency (n) and percentage (%)		Total ((N = 98)	p-value
	Control (n = 49)	Intervention (n = 49)		
1. Age				0.162
18–50	13(26.6)	12(24.5)	25	
51–70	30(61.2)	27(55.1)	57	
≥71	6(12.2)	10(20.4)	16	
2. Gender				
Male	35(71.4)	31(63.3)	66	0.389
Female	14(28.6)	18(36.7)	32	
3. Race				
Malay	21(42.9)	17(34.7)	38	0.863
Chinese	19(38.7)	23(46.9)	42	
Indian	7(14.3)	7(14.3)	14	
Others	2(4.1)	2(4.1)	4	
4. Marital status				
Single	1(2.0)	3(6.1)	4	0.552
Married	36(73.5)	37(75.5)	73	
Widowed	12(24.5)	9(18.4)	21	
5. Education level				
Primary	15(30.6)	10(20.4)	25	0.593
Secondary	13(26.5)	18(36.7)	31	
College/University	12(24.5)	11(22.4)	23	
No education	9(18.4)	10(20.4)	19	
6. Working				
Yes	23(46.9)	31(63.3)	54	0.072
No	18(36.7)	8(16.3)	26	
Retired	8(16.3)	10(20.4)	18	
7. Cancer stage				
One	1(2.0)	3(6.1)	4	0.497
Two	21(42.9)	17(34.7)	38	
Three	27(55.1)	29(59.2)	56	
8. Cancer cycle				
One	1(2.0)	1(2.0)	2	0.247
Two	5(10.2)	7(14.3)	12	
Three	22(44.9)	13(26.5)	35	
Four or more	21(42.9)	28(57.1)	49	
9. Pain chemotherapy				
Yes	33(67.3)	33(67.3)	66	1.000
No	16(32.7)	16(32.7)	32	
10. Fear of side effects				
Yes	40(81.6)	46(93.9)	86	0.121
No	9(18.4)	3(6.1)	12	
11. Cancer support group				
Yes	27(55.1)	23(46.9)	50	0.419
No	22(44.9)	26(53.1)	48	

Test used: Chi-square test

Table II: The comparison of depression mean score changes between the control and intervention groups across three follow-ups

Outcome measure	Mean ± SD		Mean difference (95%CI)	Independent t-test	p-value
	Control group (n = 49)	Intervention group (n = 49)			
Baseline	8.02 ± 5.039	8.55± 5.144	–0.531	–0.516	0.607
First follow-up	8.18 ± 4.969	7.94 ± 4.589 (–1.673, 2.163)	0.245	0.253	0.800
Second follow-up	8.29 ± 4.873	7.14 ± 4.765 (–0.790, 3.076)	1.143	1.174	0.243
Third follow-up	8.20 ± 5.046	6.27 ± 4.305 (0.058, 3.820)	1.939	2.046	0.043*

Note: *Significant at $p < 0.05$

Table III: The comparison of the effectiveness of the proposed module on depression between the control and intervention groups over time

Source	Type III sum of squares	Degree of freedom(df)	Mean square	F	p-value	Partial Ƞ2 (Effect size)
Group	47.880	1	47.880	0.533	0.467 (6.0%)	0.006
Time	61.620	1.465	42.068	14.880	< 0.001* (13.4%)	0.134
Group*Time	84.579	1.465	57.742	20.424	< 0.001* (17.5%)	0.175

Note: *Significant at p < 0.05

Table IV: The comparison of the effectiveness of the developed module on social support between the control and intervention groups over time

Source	Type III sum of squares	df	Mean square (Effect size)	F	p-value	Partial Ƞ2
Group	2.949	1	2.949	0.008	0.931	0.001 (0%)
Time	108.510	1.533	70.787	5.082	0.013*	0.050 (5.0%)
Group*Time	43.316	1.533	28.258	2.029	0.146	0.021 (2.1%)

Note: *Significant at p < 0.05

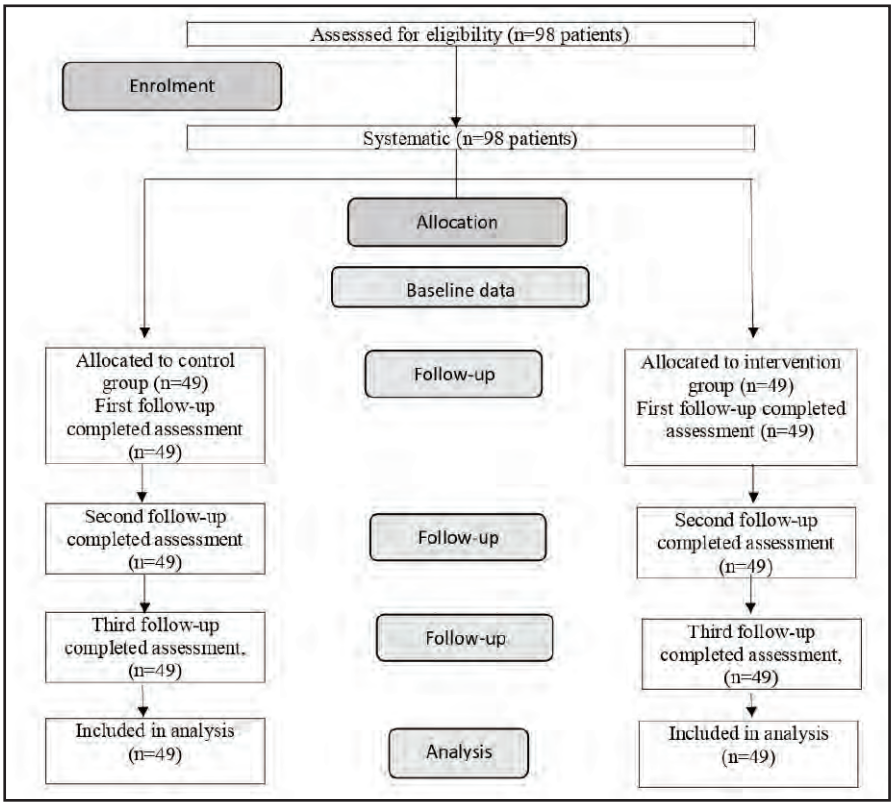

Fig. 1: CONSORT diagram of the study

observed, ensuring that both categories had similar outcome measures before the proposed intervention module was introduced.

Based on the age distribution results, most participants in the intervention and control groups were between 51 and 70 years old, recording 55.1% and 61.2%, respectively. The data also indicated that the highest percentage of participants were Chinese males. Most patients were also married, 75.5% and 73.5% of the participants in the intervention and control groups, respectively.

In the intervention group, 36.7% of patients in the intervention group attended secondary school, while 30.6% of the participants in the control group received primary education. A total of 63.3% of patients in the intervention group were employed, whereas 46.9% of their control counterparts were employed.

A majority of participants in both groups were in stage 3 of cancer and were receiving four or more cycles of chemotherapy. Moreover, numerous participants conveyed worries about chemotherapy pain and side effects. Nonetheless, a majority of patients in the intervention group did not participate in any cancer support groups.

The Effectiveness of the Intervention on Depression

The current study compared the depression mean score alterations between the control and intervention groups across three follow-ups (see Table II). At baseline, there were no significant differences in depression (p=0.607) between the intervention and control groups. Initially, no statistically significant differences in mean depression ratings were observed between the intervention and control groups at baseline (mean difference=-0.531, 95% CI=-2.573, 1.511. However, at the first follow-up (Mean=7.94, SD=4.589 in the intervention group, a significant decrease in mean score compared to the control group was observed in Depression. Positive significant changes were noted in the second follow-up (Mean=7.14, SD=4.765) and third follow-up (M=6.27, SD=4.305) follow-ups.

Table III summarises the effectiveness of the module implemented in this study on depression between the control and intervention groups over time. The results revealed that the assumption of sphericity was violated [Mauchly's test (χ2) =159.299 p<0.001]. Consequently, Greenhouse-Geiser corrected estimates were applied during the interpretation of the results.

For the group variable, no notable variation was observed regarding the primary effects (F=0.533, p=0.467, partial η^2=0.006). Nonetheless, significant differences were documented for the time variable (F=14.880, p<0.001, partial η^2=0.134) and the interaction between groups and time (F=20.424, p<0.001, partial η^2=0.175). The participants in the control group recorded increased depression, whereas the patients who received the intervention indicated improvement with each counselling session.

The Effectiveness of the Intervention on Social Support

The comparison of mean score changes in social support between the control and intervention groups across three follow-ups. At baseline, the social support mean scores between the groups were not considerably different (mean difference =–1.204, 95% CI =–5.467, 3.059, p=0.576). Similar findings were recorded for the first (mean difference =–0.041, 95% CI=–3.974, 3.892, p=0.984), second (mean difference=–0.102, 95% CI =–4.034, 3.830, p=0.959) and third (mean difference=0.653, 95% CI=–3.434, 4.740, p=0.752) follow-ups.

The effectiveness of the module on depression in the control and intervention groups over time is compared in Table IV. Greenhouse-Geiser corrected estimates were employed during result interpretation [Mauchly's test (χ^2)=161.184, p<0.001] as the assumption of sphericity was violated. No notable variations were observed for the primary effects regarding the group variable (F=0.008, p=0.931, partial η^2=0.001) and the interaction between group and time (F=2.029, p=0.146, partial η^2=0.021). Nonetheless, a significant difference was documented for time (F=5.082, =0.013, partial η^2=0.050). The patients in the intervention group demonstrated improved social support at baseline and first and second follow-ups, which declined during the third follow-up.

DISCUSSION

The Effectiveness of the Intervention on Depression

Psychiatric comorbidities, including depression, have been frequently observed in cancer patients. The illnesses can significantly impact the overall well-being and functioning of the patients.[7] A substantial number of CRC patients in the control and intervention groups of this study also documented notable depression scores, indicating their susceptibility to psychological disorders. Consequently, considering pharmacological and non-pharmacological approaches in targeting the obstacles faced by CRC patients undergoing chemotherapy is essential.

Education and counselling are vital to cancer patients, particularly in managing depression and stress.[8] Counselling offers the patients invaluable mental support and professional assistance, aiding in self-management and coping with overwhelming circumstances. Pharmacists also critically contribute to collaborations with healthcare professionals by educating and counselling CRC patients, promoting medication adherence and positive chemotherapy outcomes.[8]

Pharmacists are involved in cancer patient care to surpass its oncology focus. The strategy adopts a comprehensive management approach by identifying and addressing co-existing health conditions that might affect the patient.[9] Pharmacists possess the necessary knowledge to understand the interactions between all the medications a patient is prescribed, including for cancer treatment.[10]

In this study, the patients in the intervention group recorded considerably reduced depression from the baseline until the third follow-up. The results indicated that repetitive counselling was effective in addressing psychological issues in CRC patients. Moreover, the effect size for depression across time increased based on the pairwise comparisons [baseline versus (vs) the 1st, 2nd, and 3rd follow-ups, and the 1st vs the 2nd, the 1st vs the 3rd, and the 2nd vs the 3rd follow-ups]. The results revealed that repetitive counselling considerably diminishes depression scores. Conversely, no significant variation was demonstrated by the control group. The findings emphasised the vital role pharmacists play in improving depression among CRC patients undergoing chemotherapy through repetitive counselling sessions. Periasamy et al. (2017) reported similar results, where depression was significantly reduced following pharmacist counselling therapy for cancer patients undergoing chemotherapy.[8] In another study, Staynova et al.(2024)

noted that repetitive counselling by pharmacists enhances the mental state of cancer patients and improves their quality of life.[11]

Frequently spending time with CRC patients and engaging with them positively influences their views, perceptions, and self-management of the disease. Consequently, the patients exhibit better psychological health, as evidenced by the significant reduction in depression scores.[12]

The Effectiveness of the Intervention on Social Support

Patients diagnosed with CRC benefit from the social support their friends and family provide considerably. The support is crucial in assisting them navigate the various challenges that arise from the disease and its treatment. Tachi et al.(2015) noted that CRC patients may experience depression and anxiety at varying stages, such as while waiting for test results, upon receiving a diagnosis, during treatment, and when anticipating cancer recurrence.[13] The psychological disorders and physical effects are associated with a notable death risk, poor treatment adherence, inadequate pain management, and a desire for long-term care.

Social support from loved ones has positive effects on CRC patients. Tachi et al.(2015) indicated that such support is correlated to improved psychological wellness, overall quality of life, and physical health outcomes.[13] In this study, the baseline social support scores in the intervention group recorded a significant increase until the third follow-up, demonstrating the effectiveness of repetitive counselling in enhancing social support for patients suffering from CRC.

Based on the pairwise comparison results (between baseline and the 1st, 2nd, and 3rd follow-ups, and between the 1st and 2nd, between the 1st and 3rd, and between the 2nd and 3rd follow-ups), the effect size for social support scores consistently rose over time. The data suggested that the continual increment in social support scores throughout the study period was due to repetitive counselling. Conversely, no notable variation was recorded by the control group. The patients in the control group were not motivated to seek additional social support during the follow-up assessments.

Counselling interventions can improve the social support received by cancer patients. A cancer diagnosis can negatively affect patients' self-perception due to physical appearance alterations, the stigma associated with the disease, job loss, limitations in daily activities caused by treatment and the disease itself, and challenges of adapting to post-cancer therapy.[13] Nonetheless, consistent counselling throughout treatment might enhance social support, enabling CRC patients to address the issues.

The significant improvements in physical and psychological wellness documented by the participants in this study suggested potential awareness, self-esteem, and self-management improvement, contributing to their ability to receive social support and resume normal social activities. The findings also aligned with the previous investigations in Malaysia and China.[8] The articles documented enhanced cancer patients' self-esteem, social interaction, and overall quality of life with repetitive counselling.[12] Moreover, the intervention offers crucial mental support and guidance in understanding CRC, which is vital for motivating patients to adhere to chemotherapy.[14,15]

STRENGTHS AND LIMITATIONS

The results provided insights that might assist future studies to recognise the unique requirements of cancer patients receiving chemotherapy. This study were evaluated using self-questionnaire instruments that were self-administered. This approach is subjective and may make it difficult to differentiate symptoms from cancer or chemotherapy, as participants may report bias. Importantly, there was no intervention or educational program for the control group. Although this procedure was used to create a standard comparison group, we cannot exclude the possibility that patients in the control group were exposed to other sources of information. Moreover, pharmacists doing repetitive counselling have not been widely studied among CRC patients in Malaysia, and this study is the first attempt with CRC patients. Thus, this trial provides fundamental data and information and creates opportunities for further counselling research in CRC patients. Nevertheless, the findings significantly highlighted the importance of counselling for CRC patients receiving chemotherapy.

CONCLUSION

The participants in the intervention group reported a significant decrease in depression scores at the third follow-up and improved social support from the repetitive counselling sessions. Conversely, no positive outcomes were documented by the control group. The preferred effects of the counselling contents on aspects regarding medication adherence, treatment compliance, comprehension of the potential side effects of chemotherapy, and self-management care engagement might be the predominant force of the outcomes in the intervention group. The module developed in the present study can be considered in hospital settings under the Ministry of Health Malaysia and private hospitals with chemotherapy facilities. The framework empowers pharmacists to provide personalised care and address the physical challenges induced by chemotherapy. Furthermore, the module enables individual care while addressing depression and social support. Repetitive counselling sessions throughout treatment cycles also allow ongoing evaluation of the efficacy of the module in aiding patients with CRC.

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