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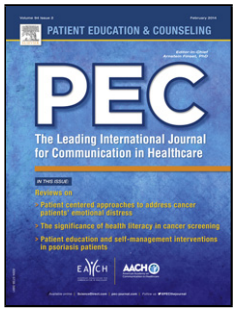

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Effectiveness of chemotherapy counselling on self-esteem and psychological affects among cancer patients in Malaysia: Randomized controlled trial

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Highlights

- Patients counselling improves outcomes
- Pharmacists play big role among cancer patients during their chemotherapy treatment
- "Managing Patients on Chemotherapy" module use as a guide for counselling
- Repetitive counselling for cancer patients improve their self-esteem
- Repetitive counselling for cancer patients decrease their anxiety and depression

Abstract

Objectives: The **aim of this** study was to implement and evaluate the outcomes **of** chemotherapy counselling based on the "Managing Patients on Chemotherapy" module on self-esteem and **psychological affect** (anxiety, depression) of cancer patients by pharmacists in ten selected government hospitals in Peninsular Malaysia.

Methods: A randomized control trial was conducted among 2120 cancer patients from April 2016 to January 2017 in ten selected government hospitals in Peninsular Malaysia. Cancer patients were randomly assigned to intervention and control groups. The intervention group received chemotherapy counseling by pharmacists based on the "Managing Patients on Chemotherapy" module. The outcomes were assessed at baseline, 1st, 2nd and 3rd follow-ups after counseling. In the course of data analysis; independent sample t-test, chi-square and two-way repeated measures ANOVA were conducted.

Results: Mean scores of self-esteem in the intervention group had significant difference in comparison with those of the control group in the 1st, 2nd and 3rd follow-ups after counselling **(P<0.0001).** Also, among those with depression and anxiety at baseline, there was reduction in depression and anxiety scores after the 1st, 2nd and 3rd follow-ups after counseling ($p<0.05$).

Conclusion: Repetitive counselling by pharmacists based on the "Managing Patients on Chemotherapy" module had positive effect on improving self-esteem and psychological **affect** of cancer patients undergoing chemotherapy in Peninsular Malaysia.

Practice Implications: This module can be used for all Malaysian cancer patients undergoing chemotherapy to **improving self-esteem and psychological affect**.

Keywords: Cancer patients, counselling, pharmacist, self-esteem, psychological **affects,** Malaysia

1. Introduction

Cancer is a major health problem in develop and developing countries [1]. Right now, the deaths from cancer are increasing in the world, with an estimated 9 million people dying from cancer in 2015 and estimated 11.4 million dying in 2020 [2]. In treatment of cancer, chemotherapy alone or in combination with radiotherapy and surgery plays an important role. The chemotherapy is an intense and cyclic treatment and unlike surgery has many side-effects like hair loss, nausea, vomiting, and diarrhoea.

Long periods of treatment, repeated hospitalizations, inability to readjust to the social and professional life and side-effects of chemotherapy can affect the psychological status of these patients. All these including knowledge of having cancer can increase anxiety and depression, as well as lower self-esteem for cancer patients [3, 4, 5].

Recent meta-analyses showed one-third of cancer patients are affected by common mental disorders, from which depression has been the most common [6, 7]. Anxiety and depression are **mental health problems** which impact on morbidity and mortality through deterioration of quality of life, difficulties of getting treatment, problems in communication with family, friends and carers, increasing risk of suicide and reduce expectation of survival [8-10]. Saniah et al. [11] demonstrated the prevalence of depression was 19.1% and 24.1% for anxiety in 2010 but now this rates have increase to 22% for depression and 31.7% for anxiety in 2015 among cancer patients in Malaysia [12].

Self-esteem is defined as one's overall evaluation of one's worth, based on the positive and negative self-perceptions that make up one's self-concept [13]. As for self-esteem, it is a personal concept that can affect different aspects of life in individuals [14]. Cancer patients undergoing chemotherapy often suffer from loss of self-esteem because of change in

physical appearance, the difficulty of managing the treatment and side effects, and re-adaptation after treatment [15, 16].

Nowadays, the field of pharmacy is growing rapidly, with emphasis on disease management to improve patient care [17]. Ruder et al. [17] reported the initial duties for the pharmacist included mixing and dispensing of parenteral chemotherapy, but now, they have started interacting with patients and provide supportive care issues (e.g., side effects of chemotherapy drugs, their mechanisms of action, and answering drug questions) [17]. Unfortunately, in Malaysia there is currently no standard guideline/module for pharmacist to counsel patients' on their chemotherapy drugs or side effects [18]. Therefore, they have to depend on their knowledge and experience in helping cancer patients to cope and overcome any side effect of chemotherapy.

The chemotherapy module was developed to address many side-effects and concerns of patients undergoing chemotherapy. By counselling these patients, it was found that many of the side-effects had reduced, mainly physical and psychological. The smaller pilot randomised control trial (RCT) found a reduction in depression and anxiety as well as improvement of self-esteem among the respondents [18, 19]. In current study based on the focus group discussion among patients undergoing chemotherapy in pilot study and results obtained from pilot study [18], researchers **chose** the three patient-report outcomes (depression, anxiety and self-esteem).

1.1 Purpose

The aim this study was to implement and evaluate the outcomes of chemotherapy counselling based on the "Managing Patients on Chemotherapy" module on self-esteem and **psychological affect** (anxiety, depression) of cancer patients by pharmacists in selected government hospitals with oncology facilities in Peninsular Malaysia.

2. Material and methods

2.1 study procedure

2.1.1 Study design

A **Multi-centre** Randomised Control Trial (RCT) study was conducted from April 2016 to January 2017. **The study ran in** ten government hospitals with oncology facilities. Each of the ten hospitals were selected from ten different state in Peninsular Malaysia. The locations were chosen based on the availability of oncology facilities in each hospitals. This is an extended study from a previous study by Periasamy et al. [18] which was conducted in only one state in Peninsular Malaysia.

Approval from Ministry of Health Malaysia (Ref no. (12)KKM/NIHSEC/P16-354), National Medical Research Registry (Ref no. NMRR-15-2299 -28299(IIR)), Universiti Putra Malaysia Ethical Committee (Ref no. UPM/TNCPI/RMC/1.4.18.1 (JKEUPM)/004) as well as the hospital directors of the selected hospitals were obtained before starting the study. A written consent was taken from each respondent before conducting the study.

2.1.2 Recruitment and eligibility screening

All Malaysian cancer patients **aged 18 years and above** with any type or stage of cancer (stage 1-4), and undergoing first and second cycles of chemotherapy treatment in government hospitals in Malaysia were included in this study. Patients were excluded if they had been diagnosed of any psychiatric disorders based on patients' medical records, had severe communication problems such as hearing or speech difficulties and those who were undergoing the third cycle of chemotherapy onwards. One pharmacist (site investigator), served as a contact person for each selected hospital and was responsible for the recruitment

of patients. The recruitment procedure is identical at each hospital according to the following step-by-step routine:

1. Potentially eligible cancer patients were identified based on the list of cytotoxic drug reconstitution (CDR), Pharmacy Department **of the participating hospitals**.
2. Patients identified as potentially eligible in step one were informed about the study verbally as well as through written study information.
3. If the patients wanted to participate in the study and fulfilled the inclusion criteria, informed consent was obtained.

Patient recruitment was conducted on a daily basis where consecutive patients attending participating hospitals for chemotherapy were approach to participate. The recruitment process continued until a maximum sample size (214 patients) was obtained for both groups at each selected hospital. Furthermore, to facilitate the recruitment of patients across all hospitals, a recruitment guideline was prepared which described each procedure in detail.

2.1.3 Sampling Method and Randomization

The multistage random sampling method was used for selecting participants. First of all, 10 states out of 13 states in Peninsular Malaysia were selected randomly. Due to limited resources for investigators to undertake traveling to East Malaysia, Sabah and Sarawak were not included in this study. In the second stage, based on the list of government hospitals with oncology facilities which was obtained from the Ministry of Health, Malaysia, one hospital randomly chosen from each state by using the random number table (total 10 hospitals selected).

The list of all eligible cancer patients which was obtained from CDR, Pharmacy Department of the participating hospitals served as a sampling frame. The eligible patients were randomly assigned into the intervention and control groups from the sampling frame, by using the even and odd numbers selection. The even numbers were assigned to the control group, while the odd numbers were assigned to the intervention group. **The allocation of patients into the intervention and control groups were based on the sampling frame; not the medical record numbers.** The randomization list was held at each site. There was no stratified randomisation for any characteristics of cancer patients. **The allocation sequence was generated by site investigators which did not know which group allocation related to which number and participants also were not aware of group assignment**. Researchers selected one intervention and one control group in each hospital. In order to control for contamination between groups; participants were selected from different wards in each selected hospital. To ensure confidentially, unique code numbers were given to each participant in the intervention and control groups, and these codes were used to identify the participants on the questionnaires.

2.1.4 Development of intervention

The educational module entitled 'Managing Patients on Chemotherapy' was used in this study. This module was developed and tested in 2013 by Periasamy et al. [18] among cancer patients in a selected government hospital in Seremban, Malaysia. The content of the education module includes; introduction, preparation for chemotherapy, managing chemotherapy side effects, chemotherapy and emotions (Refer to table 1 for detail content of education module) which should be used by the pharmacists during the counselling sessions. This educational module was developed by Periasamy et al. [18] based on the following steps:

1. Focus group discussion (FGD) among a group of cancer patients undergoing chemotherapy which was not included in the main study.
2. Some relevant information from the "Chemotherapy and You" module by the National Cancer Institute (NCI) [20, 21] was added.
3. An evaluation among pharmacists working in chemotherapy units from several hospitals was conducted to determine what information pharmacists would need in the module.
4. All feedback from the FGD, pharmacists' evaluation and information from "Chemotherapy and You" was incorporated into the educational module of 'Managing Patients on Chemotherapy'.
5. The content of the final version of this education module was checked by a group of experts which consisted of a family medicine consultant, psychologist, public health consultant, pharmacist, nutritionist and oncologist.
6. The final content of the education module was tested among 40 cancer patients other than the actual study respondents for acceptability and comprehension.

2.1.5 ***Pilot study of the chemotherapy counseling intervention***

A randomized controlled trial was conducted among 162 oncology patients undergoing chemotherapy from July 2013 to February 2014 in a government hospital with oncology facilities in Malaysia. Participants were randomized to either the intervention group or the control group. The chemotherapy counseling using the module on 'Managing Patients on Chemotherapy' by Pharmacists was delivered to the intervention group. The outcome measures were assessed at baseline, first follow-up and second follow-up and third follow-up post-intervention. The module on 'Managing Patients on Chemotherapy' along with repetitive counseling by pharmacists has been shown to be effective in improving psychological affects and self-esteem among patients undergoing

chemotherapy. The detail information of results is available in study by Periasamy et al. [18].

2.1.6 *Intervention*

The intervention group participated in the chemotherapy consultation sessions which covered all contents of the "Managing Patients on Chemotherapy" module during their baseline, 1st follow-up, 2nd follow-up and 3rd follow-up sessions. The information given in each session of counselling was driven by patients experience and guided by the content of educational module. Each counselling session took place at the designated venue in the hospital and spanned about 45-60 min, ending with questions and answer and it was done before every treatment cycle. The sessions were delivered through interactive format. The chemotherapy consultation and psychological assessment was administrated by one pharmacist-in-charge for all selected hospitals which was trained by a clinical psychologist before starting the actual study.

The control group received the treatment as usual (TAU), which in Malaysia, cancer patients receive basic information about chemotherapy and side effects of chemotherapy by pharmacists only during the first session of chemotherapy. The information given is also only based on the questions the patients ask. Respondents in the control group also received the educational module at the end of study.

All cancer patients in the intervention and control groups responded to a set of validated questionnaires consisting of the Generalized Anxiety Disorder-7, Patient Health Questionnaire-9 and Rosenberg Self-Esteem Scale at baseline, 1st, 2nd and 3rd follow-up sessions prior to the implementation of the chemotherapy counselling module. The duration between each cycle ranged from 3-6 weeks, depending on the chemotherapy treatment /

cycles of the patient. The three follow ups for each patients were achieved within 3 to 5 months (12-18 weeks). Figure 1 shows the participant CONSORT diagram of both the intervention and control groups.

2.1.7 *Outcome measure*

The primary outcomes of this study were psychological **affects** (anxiety and depression), and self-esteem of cancer patients undergoing chemotherapy treatment was the secondary outcome of this study.

2.2 Instrument

All instruments used for data collection were self-administered, using the previously validated Malay language questionnaires (the National language of Malaysia) from the original instruments [22-24].

2.2.1 Socio-demographic characteristics

The socio-demographic variables contained age, gender, race, religion, marital status, education level, family income, working status, and family history of cancer (yes / no). This section also included some clinical information such as cycle of cancer treatment (first cycle/ second cycle), cancer stage (I / II/ III/ IV), type of cancer treatment (chemotherapy / chemotherapy & radiation) and pain due to cancer (yes / no).

2.2.2 *Patient Health Questionnaire-9 (PHQ-9)*

The validated Malay version of the PHQ-9 with good specificity of (82%, 95%CI 74% to 88%) and sensitivity (87%, 95% CI 71% to 95%) was used to assess the presence of depression in this study [22]. The PHQ-9 is a self-report instrument which assesses the presence of depression and other mental disorders based on the 9 criteria of DSM-IV [25]. It consists of 9 items, each item scored from 0 (not at all) to 3(nearly every day), with an overall range score of 0-27. In this study a threshold score of 10 or above on the PHQ-9 was

considered as the presence of depression among participants. A cut off point of 10 and above was used as it has the optimum level of specificity and sensitivity [22].

2.2.3 Generalized anxiety disorder-7(GAD-7) questionnaire

The GAD-7 is a self-report instrument for measuring GAD, Post-Traumatic Stress Disorder (PTSD), panic disorder, and social anxiety [26]. The GAD-7 consists of 7 items with scores ranging from 0 to 27 and each item was scored from 0 (not at all) to 3 (nearly every day). In this study, the presence of anxiety was determined by using a cut-off point of 8 and above on the GAD-7 [23]. **The validated Malay version of GAD-7 which was found to have good specificity (94%, 95% CI 88-97) and sensitivity (96%, 95% CI 61-87) was used in this study [23].**

2.2.4 Rosenberg Self-Esteem Scale (RSES)

The Rosenberg Self-Esteem Scale (RSES) is a self-report instrument which was developed and validated by Morris Rosenberg for evaluating individual self-esteem [27]. **The validated Malay version of Rosenberg self-esteem scale with Cronbach's alpha=0.8 was used in this study [24].** It consists of 10 items related to self-esteem measuring negative and positive feeling about the self. For each item, respondents were asked to using a four-point Likert scale ranging from "strongly agree" (1) to "strongly disagree" (4). The higher scores indicated higher self-esteem among participants.

2.3 Sample size calculation

Sample size of this study was calculated based on the Rosner formula [28] which is suitable for Randomised Control Trial studies. In order to achieve 90% power (2-sided alpha p=0.05) to detect a group difference of 20% [29] and an estimate of 20% non-response rate, 1070

cancer patients in each arm were required, with a final sample size of 2140 respondents from all 10 selected government hospitals in Peninsular Malaysia.

2.4 *Data analysis*

The Statistical Package for Social Science (SPSS) version 22.0 was used for data analysis. The outcome of interest was anxiety, depression and self-esteem among cancer patients. Descriptive statistics such as frequency, percentage, mean and standard deviation were used to describe the characteristics of cancer patients in intervention and control groups. The appropriate inferential tests such as t-test and chi-square were used for comparison between intervention and control groups, at baseline. The two-way repeated measure ANOVA was used to measure the changes in the mean score of self-esteem from baseline to first, second and third follow up between intervention and control groups. The Cochran's Q test was used to assess the difference in proportion of anxiety and depression within intervention and control groups over the period of study. The level of significance was set at $p<0.05$.

3. Result

3.1 Response rate

Among those who initially agreed to participate in this study (2140), 20 dropped out for a variety of reasons (e.g. unwillingness for continuing in the study, moving to other hospitals, medical illness, and time schedule conflict). As a result, 1060 cancer patients in the intervention group and 1060 cancer patients in the control group completed the study after 3 times repetitive counselling, giving a response rate of 99.11% (Figure 1 shows detail of drop out of participants at each counselling session in both groups).

3.2Baseline data

The cancer patients (n=2120) who participated in this study were assigned to the control (n=1060) and intervention (n=1060) groups. The majority of participants were female 1203

(65.7%), Malay 1339 (63.2%), married 1450 (68.9%) and under the first cycle of treatment 1303(61.5%). Approximately 70% of the participants had depression, while 1954 (92.2%) had anxiety. The detail information of characteristics of cancer patients are presented in Table 2. At baseline also, both intervention and control groups were matched with regards to socio demographic, clinical factors, psychological **affects** and self-esteem (Table 2).

3.3 Changes in depression and anxiety after counselling

Table 3 shows the prevalence of depression and anxiety among all cancer patients at baseline, first, second and third counselling sessions (follow-ups). Based on the results, 745 (70.3%) of the participants in intervention group had depression whereas in the control group 737 (69.5%) had depression at the baseline. The percentage of those who had anxiety was 965 (91.0%) in the intervention group and 989 (93.3%) in the control group. At baseline, no significant differences in the depression ($p=0.70$) and anxiety ($p=0.06$) were found between intervention and control groups. Both groups differed significantly in terms of their rates of depression and anxiety over time (1^{st}, 2^{nd} and 3^{rd} follow-up sessions) ($p<0.05$).

Table 4 shows changes in depression and anxiety among those with depression and anxiety at baseline between groups over the counselling sessions. Based on the results, among those with depression at baseline, 606 (81.3) in the intervention group and 673 (91.3%) in the control group had depression after first session of counselling, while 341 (45.8%) in the intervention group and 606 (82.2%) in the control group had depression after the third session of counselling. Likewise, 689 (42.8%) in the intervention group and 922 (93.2%) in the control group had anxiety after the third session of counselling. Both intervention and control groups differed significantly in depression and anxiety at over time (1^{st}, 2^{nd} and 3^{rd} follow-up sessions) ($p<0.05$).

3.4 Changes in anxiety and depression between intervention and control groups over times

Figure 2 compares changes in depression in the intervention and control groups. As shown in this figure there was a significant decrease in depression after the first (57.2%) and second (33.9%) counselling sessions in the intervention group; however there was a slight increase (43.5%) after third counselling session (p=0.001). While in the control group, there was no significant decrease in depression after the third follow-up (p=0.052). This figure indicates 43.5% of the patients in the intervention group and 80.7% of patients in control group had depression after the third session of counselling.

Figure 3 shows comparison of changes in anxiety rate in the intervention and control groups. In the intervention group, there was significant decrease in anxiety rate from baseline (91%) to the second session of counselling (68.5%) and anxiety increased after the third session of counselling (71.4%). While in control group, there was no significant decrease in anxiety observed during the third session of counselling. This figure indicates 71.4% of cancer patients in the intervention group and 93% in the control group had anxiety after completion of the third counselling session.

3.5 Changes in self-esteem after counselling

The comparison mean scores between the intervention and control groups at baseline, 1th follow-up, 2nd follow-up and 3rd follow up are shown in table 5. Based on the results, there were no significant differences in self-esteem between intervention and control groups at baseline (t=1.47, p=0.14). However, the mean differences of self-esteem 4.07(95% CI 3.70-4.37) for the intervention group was significantly higher than the control group. Also, the intervention group had statistically significant improvement in the self-esteem (F=68.15, p=0.000) over time.

4. Discussion and Conclusion

4.1 Discussion

Depression and anxiety are the two most common psychiatric comorbidities among cancer patients and both can effect on functional and overall health of cancer survivors [29, 30]. The management of depression and anxiety not only requires the appropriate medicine but also require vigorous education and counselling for the patients [30]. Counselling is a great mental support and provides professional assistance for patients in coping and management of their current situation [31].

In hospital settings, pharmacists play an important role in collaborating with health care professionals and can contribute to positive outcomes of chemotherapy by educating and counselling cancer patients to motivate them to follow their chemotherapy regimens [32]. This also improves patients' adherence to their chemotherapy. Our results highlight the important role of pharmacists in reducing anxiety and depression and improving self-esteem among cancer patients undergoing chemotherapy by providing these chemotherapy counselling sessions. Similarly, Periasamy et al. [18] reported that counselling therapy by pharmacists had positive effect on reduction of anxiety and depression and improving self-esteem among cancer patients during their chemotherapy treatment.

4.1.1 Depression

Depression remains highly prevalent in cancer patients, and appears to have a great impact on their quality of life as well as on certain cancer outcomes, even if probably by the means of its impact on compliance, physical activity, and social support [8]. In this study also the rate of depression was high among all cancer patients (69.9%) which is similar with the results of the study done among cancer patients in Jordan [33] and China [34]. In addition, the results of this study showed that after repetitive counselling the prevalence of depression among those with depression at baseline had decrease. This significant improvement shows that

spending time with patients and frequent interactions with them positively improved the patients' view of managing their disease and caused reduction in their depression scores and pharmacists had the chance to positively impact this population as well as the outcome of their treatment [18]. This result is consistent with those of the previous studies in Malaysia [18] and India [35] which showed that repetitive counselling by pharmacists significantly decrease depression among cancer patients. Also, results of another study which was conducted among 150 patients in Kuwait showed that majority of patients were very eager to receive more information on their treatment, despite receiving information from their physician related to their disease and treatment [36]. In addition, these patients highlighted that pharmacists' counselling on drugs and their side-effects was more comprehensive than the physicians' explanation [36].

4.1.2 Anxiety

At baseline, a high proportion of cancer patients were affected by anxiety (92.2%) which included mild, moderate and severe anxiety and these rates were higher than other reported studies [37, 38]. In a qualitative study conducted by Farooque et al. [39] among 20 cancer patients in Malaysia indicated fear of side effects from chemotherapy and radiotherapy was one of the reasons for anxiety and depression among cancer patients. Furthermore, results of this study showed that in comparison to the control group there was significant improvement in the rate of anxiety over time with repetitive counselling among cancer patients in the intervention group. The findings of this and previous studies support the role of repetitive counselling for decreasing anxiety among cancer patients [18, 35].

4.1.3 Self-esteem

Self-esteem is defined as the way people see themselves. There is no doubt that diagnosis of cancer affect negatively on patients' self-esteem due to change in physical appearance,

barriers to routine activities due to disease and treatment, the stigma of disease, loss of jobs and re adaption after cancer treatment [15, 40]. However by doing counselling during patients' treatment can improve their self-esteem. In line with this, results of this study showed that cancer patients had low mean scores of self-esteem at baseline (24.41 ± 7.02); however this improved significantly after 3 times repetitive counselling (31.14 ± 5.95) compared to the control group, which is consistent with another study done in Malaysia [18] and China [41], which showed that with repetitive counselling the self-esteem of cancer patient improved.

4.1.4 Strengths and limitations

The strengths of this study was the use of a gold standard design which is a randomized control trial design, low attrition rate, large sample size, appropriate statistical test and using a new counselling method at a national level. To the best of our knowledge, this study is the first RCT study among cancer patients in Peninsular Malaysia, therefore the finding of this study can be used as fundamental data for further studies. This study also had some limitations, where a self-administered method with no objective measures to evaluate cancer patients was used. In the current study, the control group did not receive any education program during the study. The control group only received TAU. Nonetheless, they may have been exposed to other information sources including pamphlets, media or any extra information by health care professionals which could not be controlled. Since this study was done among cancer patients, the result of this study cannot be generalized to another type of disease. It is suggested that further studies be done among patients with other types of diseases to determine the role of pharmacist as a counsellor. Another recommendation is to investigate the impact of pharmacist on specific cancer patient outcomes and determining the cost effectiveness. Also, the role of pharmacist in identifying and preventing the medication errors for outpatients should be evaluated further. We would recommend an intervention

which specifically targets concern in later stage of cancer and higher severity of anxiety and depression.

Hospital level barriers differed slightly between hospitals with the main barrier being communication problems. Overcoming this barrier required establishing good relationships with staff involved, providing a clear explanation of what as required. All these began from the time of ethics approval and permission to conduct the study from the relevant authorities involved, including permission from each hospital, up to the completion of the study.

4.2 Conclusion

The results of this study revealed that majority of cancer patients had psychological problems such as anxiety and depression and low levels of self-esteem. However, this study shows that the module of "Managing Patients on Chemotherapy" together with repetitive counselling by pharmacists was effective in decreasing anxiety and depression and improving self-esteem of the oncology patients in the intervention group which hopefully results in better quality of life for the patients and their families, as well as improve their social activities in the society.

4.3 Implication to practice

The pharmacists can use this module as a guide for doing counselling among cancer patients undergoing chemotherapy to monitor chemotherapy sustained effects like psychological **affects** and self-esteem.

List of abbreviations

Randomised Control Trial (RCT), cytotoxic drug reconstitution (CDR), Focus group discussion (FGD), National Cancer Institute (NCI), treatment as usual (TAU), Patient Health

Questionnaire-9 (PHQ-9), Generalized anxiety disorder-7(GAD-7), Rosenberg Self-Esteem Scale (RSES), Statistical Package for Social Science (SPSS).

Authors' contributions

SMS, UP, LR, and SIFA designed the study. UP and SMS collected the data. MA-Z led the data analysis. MA-Z and SMS wrote and critically edited the manuscript. All authors read and approved the final manuscript.

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Availability of data and material

A request for the data and material may be made to the corresponding author of the article.

Competing interests

The authors declare that they have no competing interests.

Ethics approval and consent to participate

This study was approved by Ethics Committee of the Faculty of Medicine and Health Sciences, Universiti Putra Malaysia (Ref no. UPM/TNCPI/RMC/1.4.18.1 (JKEUPM)/004). A written consent was taken from each respondent before conducting the study.

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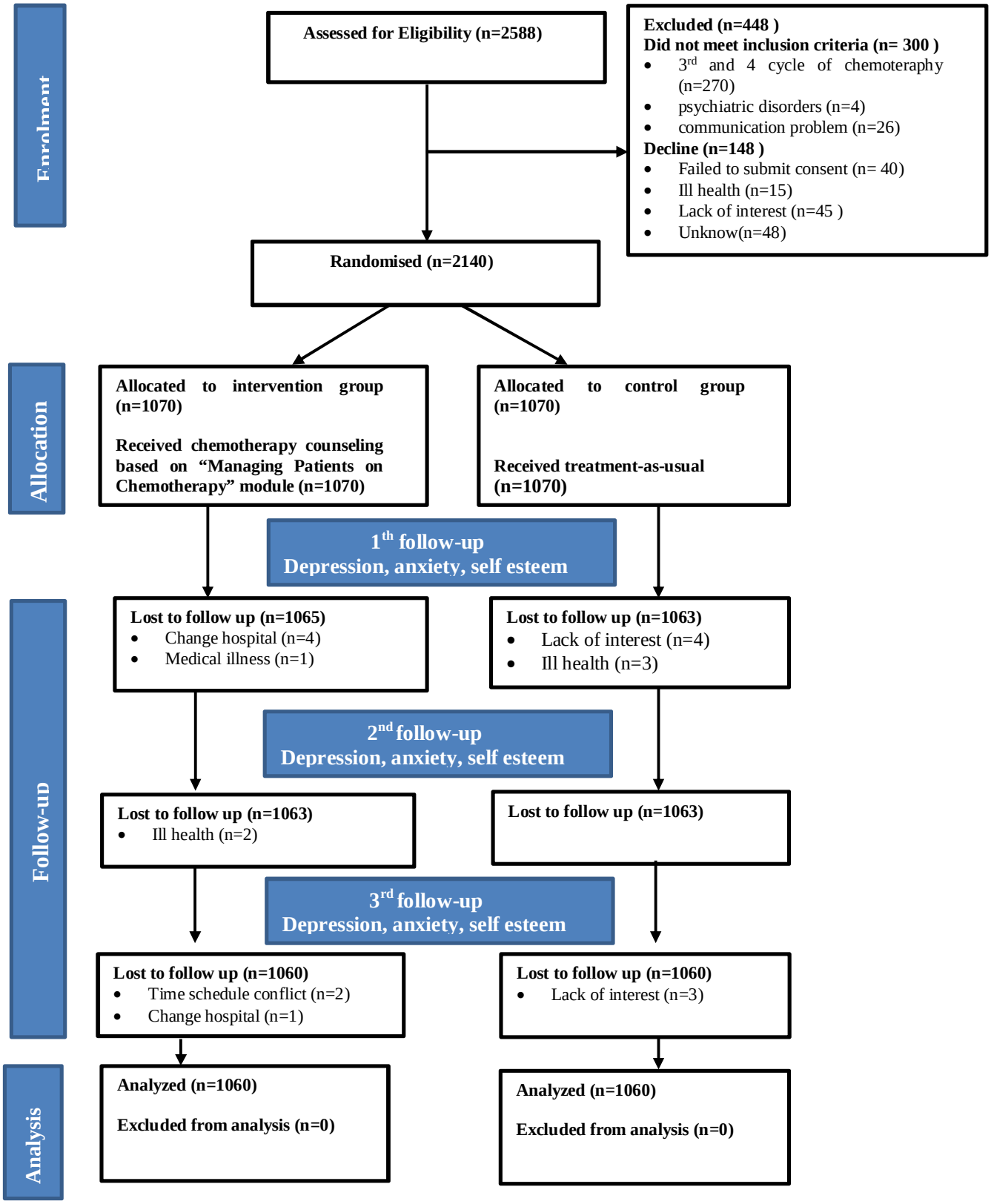
Figure 1 CONSORT diagram of study participants in control and intervention groups

Figure 2. Comparison of changes in depression in intervention and control group over times. Baseline: Before doing counselling, First: After doing first counselling session, Second: After doing second counselling session, Third: After doing third counselling session

Figure 3. Comparison of changes in anxiety in intervention and control group over times. Baseline: Before doing counselling, First: After doing first counselling session, Second: After doing second counselling session, Third: After doing third counselling session



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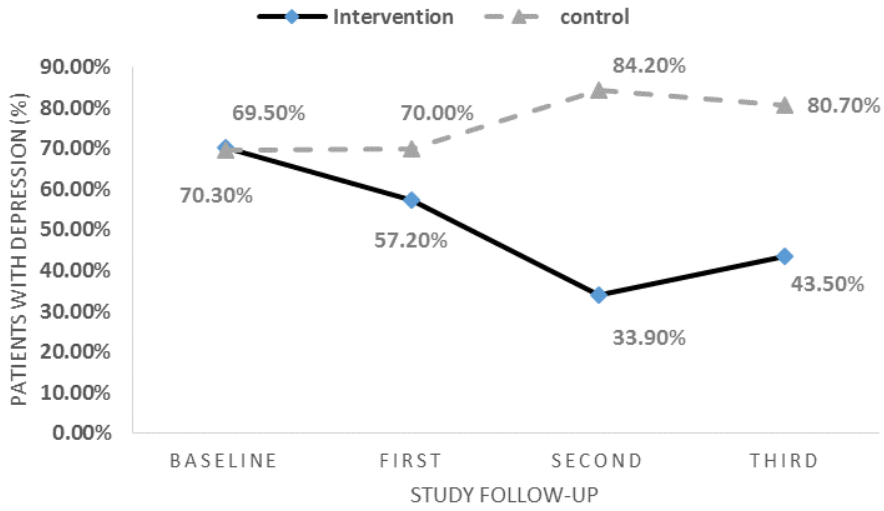
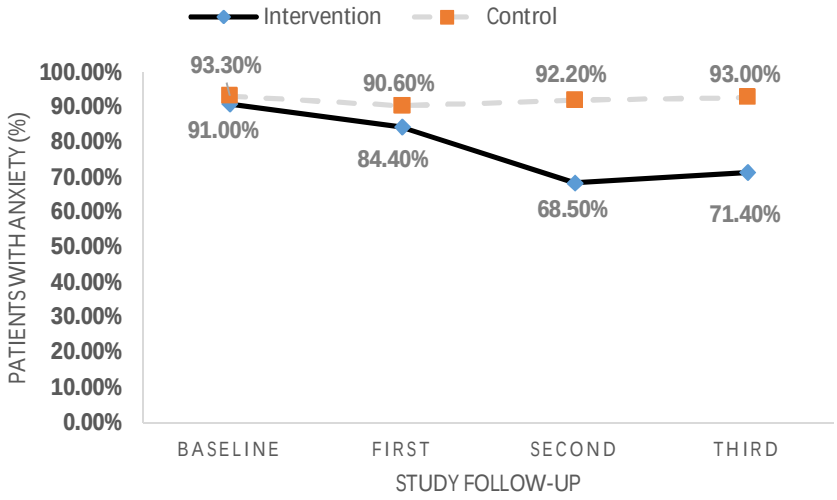


Number of participants				
Intervention	1070	1065	1060	1060
Control	1070	1063	1063	1060

Figure 2. Comparison of changes in depression in intervention and control group over times. Baseline: Before doing counselling, First: After doing first counselling session, Second: After doing second counselling session, Third: After doing third counselling session



Number of participants				
Intervention	1070	1065	1060	1060
Control	1070	1063	1063	1060

Figure 3. Comparison of changes in anxiety in intervention and control group over times. Baseline: Before doing counselling, First: After doing first counselling session, Second: After doing second counselling session, Third: After doing third counselling session

Table 1: Details content of "Managing Patients on Chemotherapy" module

Chapter	Content
Preface	
Chapter 1 **introduction**	• About chemotherapy • Causes of chemotherapy side effects • Chemotherapy drugs and potential side effects
Chapter 2 **Preparation for chemotherapy**	• Before chemotherapy (Dental, clothes, vitamin, food to eat, food to avoid) • During chemotherapy • After chemotherapy
Chapter 3 **Managing chemotherapy side effects**	• Nausea and vomiting • Hair loss/ Fatigue/anemia • Infection / Bleeding/ constipation • Mouth, gums, throat problems • appetite changes/ weight gain/ pain
Chapter 4 **Chemotherapy and emotions**	• Depression • Anxiety and fear • Managing adverse psychological effects of cancer anger

- Managing complications due to cytotoxic extravasation

HOW TO USE THIS MODULE

REFERENCES

Table 2. Characteristics of cancer patients in Malaysia (n=2120)

Characteristics	Intervention group	Control group	Total participants
	n(%)	n(%)	n(%)
Age			
<45	117(11.0%)	148(14.0%)	265(12.5%)
45-54	174(16.4%)	185(17.5%)	359(16.9%)
55-64	343(32.4%)	332(31.3%)	675(31.8%)
>65	426(40.2%)	395(37.3%)	821(38.7%)
Gender			
Male	443(41.8%)	474(44.7%)	917(43.3%)
Female	617(58.2%)	586(55.3%)	1203(56.7%)
Race			
Malay	680(64.2%)	659(62.2%)	1339(63.2%)
Chinese	246(23.2%)	257(24.2%)	503(23.7%)
Indian	130(12.3%)	130(12.3%)	260(12.3%)
Other	4(0.4%)	14(1.3%)	18(0.8%)
Religion			
Muslim	680(64.2%)	658(62.1%)	1338(63.1%)
Buddhist	246(23.2%)	258(24.3%)	504(23.8%)
Hindu	130(12.3%)	130(12.3%)	260(12.3%)
Christian	4(0.4%)	14(1.3%)	18(0.8%)
Marital Status			
Single	78(7.4%)	61(5.8%)	139(6.6%)
Married	711(67.1%)	749(70.7%)	1450(68.9%)
Widowed	140(13.2%)	149(14.1%)	289(13.6%)
Divorced	77(7.3%)	64(6.0%)	141(6.7%)
Separated	54(5.1%)	37(3.5%)	91(4.3%)

Education level			
No formal education	225(46.3%)	261(24.6%)	486(22.9%)
Diploma & less	648(52.2%)	594(56.0%)	1242(58.6%)
Degree & above	392(18.5%)	205(19.3%)	392(18.5%)
Family Income (RM)			
No income	389(36.7%)	389(36.7%)	778(36.7%)
<1500 RM	191(18.0%)	193(18.2%)	384(18.1%)
1501-3500 RM	280(26.4%)	265(25.0%)	545(25.7%)
>3501 RM	200(18.9%)	213(20.1%)	413(19.5%)
Working status			
Yes	472(44.5%)	445(42.0%)	917(43.3%)
No	389(36.7%)	389(36.7%)	778(36.7%)
Retired	199(18.8%)	226(21.3%)	425(20.0%)
Family history of cancer			
Yes	516(48.7%)	472(44.5%)	988(46.6%)
No	544(51.3%)	588(55.5%)	1132(53.4%)
Cycle of cancer treatment			
1st cycle	648(61.1%)	655(61.8%)	1303(61.5%)
2nd cycle	412(38.9%)	405(38.2%)	817(38.5%)
Cancer Stage			
Stage 1	100(9.4%)	108(10.2%)	208(9.8%)
Stage 2	165(15.6%)	158(14.9%)	323(15.2%)
Stage 3	407(38.4%)	378(35.7%)	785(37.0%)
Stage 4	388(36.6%)	416(39.2%)	804(37.9%)
Type of cancer treatment			
Chemotherapy	964(90.9%)	980(92.5%)	1944(91.7%)
Chemotherapy & radiation	96(9.1%)	80(7.5%)	176(8.3%)
Pain due to cancer			
Yes	555(52.4%)	580(54.7%)	1135(53.5%)
No	505(47.6%)	480(45.3%)	985(46.5%)
Depression			
Yes (PHQ-9≥10)	745(70.3%)	737(69.5%)	1482(69.9%)
No (PHQ-9<10)	315(29.7%)	323(30.5%)	638(30.1%)

Anxiety			
Yes (GAD-7≥8)	965(91.0%)	989(93.3%)	1954(92.2%)
No (GAD-7<8)	95(9.0%)	71(6.7%)	166(7.8%)
Self-esteem			
Mean± SD	24.41 ±7.02	24.86± 6.98	24.63 ±7.00

Table 3. Change in depression and anxiety between intervention and control group at baseline, first, second and third counselling (n=2120)

Variables	Intervention group (n=1060)	Control group (n=1060)	Statistics
	n(%)	n(%)	

Depression (Baseline)			
Yes (PHQ-9≥10)	745(70.3%)	737(69.5%)	χ^2 =0.14, p=0.70
No (PHQ-9<10)	315(29.7%)	323(30.5%)	df=1
Depression (First counselling)			
Yes (PHQ-9≥10)	606(57.2%)	742(70.0%)	χ^2 =37.68, p=0.00*
No (PHQ-9<10)	454(42.8%)	318(30.0%)	df=1
Depression (Second counselling)			
Yes (PHQ-9≥10)	359(33.9%)	893(84.2%)	χ^2 =556.28, p=0.00*
No (PHQ-9<10)	701(66.1%)	167(15.8%)	df=1
Depression (Third counselling)			
Yes (PHQ-9≥10)	461(43.5%)	855(80.7%)	χ^2 =311.04, p=0.00*
No (PHQ-9<10)	599(56.5%)	205(19.3%)	df=1
Anxiety (Baseline)			
Yes (GAD-7≥8)	965(91.0%)	989(93.3%)	χ^2 =3.76, p=0.052
No (GAD-7<8)	95(9.0%)	71(6.7%)	df=1
Anxiety (first counselling)			
Yes (GAD-7≥8)	895(84.4%)	960(90.6%)	χ^2 =18.22, p=0.00*
No (GAD-7<8)	165(15.6%)	100(9.4%)	df=1
Anxiety (Second counselling) Yes (GAD-7≥8)	726(68.5%)	977(92.2%)	χ2 =188.07, p=0.00*
No (GAD-7<8)	334(31.5%)	83(7.8%)	df=1

Anxiety (Third counselling)			
Yes (GAD-7≥8)	757(71.4%)	986(93.0%)	$\chi 2$ =169.18, p=0.00*
No (GAD-7<8)	303(28.6%)	74(7.0%)	df=1

*Significant at p< 0.05

Table 4. Changes in depression and anxiety between intervention and control group after first, second and third counselling sessions among those have depression and anxiety at baseline

*Significant at $p < 0.05$

Depression (n=1482)	Intervention group	Control group	Statistics
	n(%)	n(%)	
Depression (First counselling)			
Yes (PHQ-9≥10)	606(81.3%)	673(91.3%)	χ^2 =31.77, p=0.00*
No (PHQ-9<10)	139(18.7%)	64(8.7%)	df=1
Depression (Second counselling)			
Yes (PHQ-9≥10)	279(37.4%)	638(86.6%)	χ^2 =378.90, p=0.00*
No (PHQ-9<10)	466(62.6%)	99(13.4%)	df=1
Depression (Third counselling)			
Yes (PHQ-9≥10)	341(45.8%)	606(82.2%)	χ^2 =213.42, p=0.00*
No (PHQ-9<10)	404(54.2%)	131(17.8%)	df=1

Anxiety (n=1954)		**Intervention group (n=1060)**	**Control group (n=1060)**	**Statistics**
		n(%)	n(%)	
Anxiety (first counselling)				
Yes (GAD-7≥8)		895(92.7%)	942(95.2%)	χ^2 =5.43, p=0.02*
No (GAD-7<8)		70(7.3%)	47(4.8%)	df=1
Anxiety (Second counselling)	Yes			
(GAD-7≥8)		664(68.8%)	917(92.7%)	χ2 =180.81, p=0.00*
No (GAD-7<8)		301(31.2%)	72(7.3%)	df=1
Anxiety (Third counselling)				
Yes (GAD-7≥8)		689(42.8%)	922(93.2%)	χ2 =160.77, p=0.00*
No (GAD-7<8)		276(28.6%)	67(6.8%)	df=1

Table 5. Mean score of self-esteem between intervention and control group at baseline, first, second and third follow-ups

Variables	Baseline	1th follow-up	2nd follow up	3rd follow up	Effect of intervention	Statistics
		Mean ± SD			Mean differences (95%CI)	
Self-esteem						
Intervention Group	24.41 ± 7.02	26.84 ± 6.96	28.56 ± 6.56	31.14 ± 5.95	4.07, (3.70-4.37)	0.000*
Control Group	24.86 ± 6.98	24.85 ± 6.16	23.02±5.32	22.06±4.61	0	

SD standard deviation, CI confidence interval
*Significant at $p < 0.05$