eISSN: 2645-7687. Journal of Clinical Care and Skills. 2020;1(2):63-69

Effect of Intervention Based on 5A Self-Management Model on the Fatigue Severity of Patients with Cancer under Chemotherapy; A Randomized Clinical Trial

Journal of Clinical Care and Skills

ARTICLE INFO

Article Type
Original Research

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How to cite this article
Roozitalab M, Hosseini N, Vossoughi M, Zoladl M. Effect of Intervention Based on 5A Self-Management Model on the Fatigue Severity of Patients with Cancer under Chemotherapy; A Randomized Clinical Trial. Journal of Clinical Care and Skills. 2020;1(2):63-69.

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Article History
Received: November 6, 2018
Accepted: March 1, 2019
ePublished: June 20, 2020

ABSTRACT

Aims One of the side effects of chemotherapy is fatigue. This study was carried out with the aim of determining the effect of intervention based on 5A self-management model on the fatigue severity of patients with cancer under chemotherapy.

Materials and Methods In this randomized clinical trial conducted in 2016, 48 patients with cancer under chemotherapy, who were referred to Chemotherapy Center of Shahid Motahari Clinic of Shiraz University of Medical Sciences, were selected, using purposive sampling method, and then, divided to experimental and control group with the equal number, using block random allocation. While control group received routine treatment and care related to chemotherapy, 5A self-management model was applied for experimental group. The data gathering tool consists of a demographic questionnaire and Multidimensional fatigue inventory (MFI). The data were analyzed by SPSS 21 software.

Findings Immediately after research intervention, the fatigue severity in the intervention group(43.4±6.9) was less than this amount in the control group (46.8±12.9), but 3 months later, the fatigue severity in the control group (34.7±10.1) was more less than this amount in the intervention group (41.9±4.8; $p<0.05$). In the intervention group, the fatigue intensity immediately and 3 months after the end of the research intervention was significantly lower than the starting point of the study. In the control group, the fatigue severity decreased significantly 3 months after the end of the intervention, compared to starting point of the study and immediately after the intervention.

Conclusion 5A self-management model decreases fatigue severity of patients with cancer under chemotherapy in the intervention group.

Keywords Self-management; Fatigue; Cancer; Chemotherapy

CITATION LINKS

[1] Cancer incidence and mortality worldwide: Sources, methods and major patterns ... [2] Incidence trend and epidemiology ... [3] Managerial self-efficacy for chemotherapy ... [4] Cardiorespiratory and neuromuscular deconditioning in fatigued and ... [5] Factors predicting fatigue in breast cancer ... [6] Fatigue self-management behaviors in patients with advanced cancer: A prospective ... [7] Public health nursing - revised reprint - e-book ... [8] Screening, evaluation, and management of cancer ... [9] Cancer related fatigue and quality ... [10] Adaptation of the chronic disease ... [11] Self-management education interventions ... [12] Chronic disease management in primary ... [13] Empowerment in the self-management of hypertension ... [14] Self-management and transitions in women with ... [15] Translating what we have learned ... [16] Mechanism of engaging self-management ... [17] Long-term effect of the self-management comprehensive ... [18] The effectiveness of self management program ... [19] Effects of a self-managed home-based walking ... [20] Effects of a self-management program on ... [21] Application of the Multidimensional Fatigue ... [22] Reliability and structural validity of the ... [23] The measurement of fatigue in ... [24] Multidimensional Fatigue Inventory... [25] Randomized controlled trial of an ... [26] Patient education programs for cancer ... [27] Effects of multidisciplinary rehabilitation ... [28] Impact of chronic disease self-management ... [29] Is education an effective management strategy ... [30] A randomized controlled trial of a support group ... [31] Pilot, randomized, modified, double-blind, placebo ... [32] The effect of symptom clusters on functional ... [33] Exercise: A path to wellness during adjuvant ... [34] Effectiveness of a 12-month exercise program on ... [35] Managing symptoms in patients with advanced ... [36] Pilot randomized controlled trial of a patient ... [37] The effectiveness of nursing education as an intervention to ... [38] Evaluation of a fatigue self-management program for people with ... [39] Comparison of pharmaceutical, psychological, and exercise treatments for cancer ... [40] Fatigue in canser patients receiving ...

Introduction

Cancer is the second leading cause of death after heart disease in the United States [1]. In Iran, after cardiovascular diseases, trauma and accidents, cancer was the third most common cause of death, and its prevalence was 134 in every 100,000 people in 2013 [2]. Chemotherapy is one of the most important treatments for cancer, but it can cause side effects [3]. The most common and annoying symptom of chemotherapy is fatigue, which has been reported in 70-100% of cancer patients [4]. According to a study, three dimensions of breast cancer fatigue, including physical exhaustion due to depression, pain and consumption of Tamoxifen, emotional exhaustion associated with anxiety and depression, and ultimately cognitive tiredness with anxiety and pain [5].

Fatigue in cancer patients is a complex process, in which three types of factors are involved, including individual experiences, such as physical impairment and psychological stresses due to cancer treatment process, social limitations and its effects on quality of life and compliance with the disease. In studies, stress, nutritional disorders, vomiting and nausea and inadequate knowledge about the course of disease and treatment, anxiety and depression were some of the causes of fatigue [3, 6]. Cancer-related fatigue affects all aspects of life, including physical, mental, social and spiritual health, and can lead to reduced productivity, self-esteem and physical functioning [8, 9]. Today, except for the medication therapy, non-medication therapy methods, such as maintaining sleep hygiene, energy saving, and exercise as well as self-management interventions aimed at promoting self-efficacy can be used to reduce cancer-related fatigue [6]. A review study showed that non-medication therapy methods, such as self-management interventions in psychology, cognitive-behavioral therapy and acupressure reduce fatigue symptoms, pain, depression and anxiety in cancer patients and improve their quality of life [10].

Self-management is defined as the ability of an individual to manage symptoms of disease, treatment, physical, psychological and social complications and lifestyle change caused by chronic diseases [11]. Self-management is a general plan that emphasizes the management of problems in controlling everyday life. Effective self-management can influence individual ability in cognitive, behavioral and emotional responses to maintain a satisfactory quality of life [6]. Patients who train self-management behaviors may feel more empowered and be able to make informed decisions, cope with the treatment and side effects associated with treatment and move right toward cancer treatment. As a result, they may be more satisfied with their care and have a better experience of cancer and self-care [12].

The crucial role of nurses in self-management education to the patient, which is one of the best practices for persuading patients for behavioral changes and drug therapy, promoting health and successfully controlling disease, has been acknowledged in many studies [13]. Studies have shown that access to positive clinical outcomes is difficult or impossible if chronic patients do not participate actively in self-management and self-care programs [14]. 5A self-management model is a well-known behavior change advisory and evidence-based approach for improving behavior and health, including five stages, such as (1) reviewing patient's behaviors, beliefs and motivations; (2) counseling patients about personal health risks; (3) agreeing with patients on the realistic setting of goals; (4) helping to predict barriers and practical development; and (5) Follow-up supports [15]. Studies have been done on empowerment of patients by increasing the success of self-management skills in different groups of chronic patients. Yang *et al.* showed that self-efficacy and making patients with heart failure active have a significant relationship with self-management behaviors [16].

In a study in the United States, the quality of life of patients with breast cancer has increased by using comprehensive self-management stress program [17]. Ahmadi *et al.* showed the effect of 5A self-management model on the improvement of fatigue in patients with Sickle cell disease [18]. Also, the effects of self-management interventions along with walking at home on the reduction of fatigue in patients undergoing chemotherapy as well as its ineffectiveness of this intervention on depression have been reported [19].

Hanai *et al.* studied the effect of self-management program on constipation induced by antiviral drugs in breast cancer patients under chemotherapy and their results indicated a positive effect of self-management interventions on gastrointestinal symptoms caused by constipation and quality of life in these patients [20].

Accordingly, due to the inconsistent and in some cases contradicting results and the lack of a specific and systematic self-management program in some relevant studies and also because of the necessity of taking effective and appropriate measures to prevent, control or improve the complications of chemotherapy in cancer patients by nurses as the most important member of the care and treatment team, this study was carried out with the aim of determining the effect of intervention based on 5A self-management model on the fatigue severity of patients with cancer under chemotherapy.

Materials and methods

This randomized clinical trial was conducted on patients with gastrointestinal, skin, uterine, ovarian

and breast cancer under chemotherapy referred to Chemotherapy Center of Shahid Motahari Clinic of Shiraz in 2016.

At first, for the sample size was calculated 21 subjects using the results of study by Guccal *et al.* on fatigue variable (μ1=4.2, μ2=9.24, S1=3.35, S2=4.73) and the alpha value of 0.05 (95% confidence level) and beta of 20% (80% test power). However, considering the 40% probability of falling the number of needed samples was regarded 30 subjects in each group (totally 60 samples) [19]. Following calculating the sample size, using quadruple block random allocation, the number of subjects in the experimental and control groups were secretly determined as follows; Since the number of people in each block was 4 people, the number of blocks resulting from all sampling was 24 blocks and the estimated sample size obtained 60 subjects. Therefore, by matching 15 random numbers (1-24), using the number of the mentioned blocks, we found how to assign 60 research subjects and also assigning each number from 1 to 60 to one of the experimental and control groups.

The researcher then referred to the Chemotherapy Center of Shahid Motahari Clinic of Shiraz from the second half of September 2016 until data saturation (the second half of November) and made the patients informed about the research objectives, received the informed consent form from the subjects and distributed the demographic questionnaire and also multidimensional fatigue inventory (MFI) among 157 patients with cancer under chemotherapy. 128 patients who were willing to participate in the study completed the relevant forms, of whom 60 persons scored 40-60% for the fatigue severity and had other inclusion criteria, including ages <70 years, full conscientiousness, reading and writing skills, lack of history of seizure and mental illness, no drug addiction, and no hearing and vision problems were selected by purposeful sampling method and they received the code based on the entering of study. This code was matched with the random allocation list and samples were assigned to the experimental group or control group. During the intervention and data collection, 12 subjects according to the exclusion criteria, including unwillingness to continue cooperation, exacerbate illness and lack of exercise at home, the refusal to complete or incomplete answers were excluded in the post-test and follow-up phases of the study.

The control group received the usual care and treatment of chemotherapy, whereas the experimental group, in addition to the treatment and conventional chemotherapy treatment were subjected to the 5A self-management model-based intervention based on the on the protocol in 5 stages, including evaluation, guidance, agreement, assistance and follow-up for 4 sessions (two individual sessions and two group sessions) and reviewing patient's behaviors, beliefs and motivation, patient guidance about personal health risks, agreement with patients on the realistic setting of goals, assistance in predicting barriers, and practical development and follow-up support were considered.

Data collection tools were the demographic questionnaire (including age, sex, weight, height, marital status, educational level, occupation, place of residence, family history of cancer, type of cancer, duration of cancer, type of treatment and duration of treatment) and also the MFI.

This questionnaire was firstly developed by Smets in 1996 and can be used on patients and healthy people [21]. This 20-item questionnaire is scored as follows: questions 1, 3, 4, 6, 7, 8, 11, 12, 15, 19 and 20 are scored 1 from "Yes, it is completely correct" (score 1) to "No it is completely wrong" (score 5) and also the questions 2, 5, 9, 10, 13, 14, 16, 17, and 18 are reversely scored from "yes, it is completely correct" (score 5) to "good is completely wrong" (score 1). The scores of this questionnaire are ranged from 20 to 100, and a higher score indicates a higher level of fatigue. It has used to assess various fatigue types, including Parkinson's patients, cancer patients under radiotherapy, and chronic patients [23] and not only its validity has been confirmed in Iranian studies, its reliability has been confirmed by Cronbach's alpha of 0.89 [24]. MFI in addition to the baseline, as a pre-test was completed immediately and 3 months after the intervention as the post-test and follow-up by all subjects.

This clinical trial was approved by the Yasouj University of Medical Sciences Research Ethics Committee (Ethics code: IR.YUMS.REC.1395.83) and was registered on the Iranian registry of clinical trial (IRCT2016080829266N1). All ethical considerations, such as obtaining informed written consent of samples, the right to participate or not in research, and permission to withdraw the study at any time, confidentiality of all collected information and their use in general and only for performing the research, no changes in used drugs and no deprivation of subjects from standard treatment and care were observed. Also, the research did not have any additional financial burden for patients, their families and insurers, and those who participated in the research, if they wished, were informed about the results of their individual measurements as well as general findings from the research.

The collected data from 48 subjects, which was higher than the estimated sample size without considering the possible falling (42 subjects in two groups of 21) was analyzed by a statistician who until the end of the analysis blind to the codes assigned to each of the subject in two groups by SPSS 21 software using descriptive statistics, including mean, standard deviation and frequency distribution, and inferential statistics, such as independent t test, Mann-Whitney test and Chi-

square test to compare the field and dependent variables between the experimental group and control group at the baseline at a significant level of 0.05. Also, to compare the mean of fatigue severity in the pre-test and post-test between the experimental and control groups based on time/group (inter-group comparison) comparing their differences in terms of each of the studied groups (intra-group comparison), the repeated measures ANOVA and Bonferroni post-hoc test were used. In order to eliminate the effect of this inconsistency, the fatigue severity variable in the pre-test was considered as a covariance.

Findings

Of the 48 cancer patients under chemotherapy, 13 patients (27.1%) were male and 35 patients (72.9%) were female. The mean height, weight, duration of suffering from cancer and duration of chemotherapy were 160.1±7.2 cm, 64.2±7.1 kg, 27.2±23.4 months and 23.9±23.7 months in the experimental group, and 15.9±6.8 cm, 64.7±7.3 kg, 28.8±20.2 months and 21.6±17.4 months in the control group, respectively. The studied groups were homogenized in terms of the above quantitative variables at the baseline ($p>0.05$). in addition, at the baseline, there was no significant difference between the groups in terms of qualitative variables such as age group, gender, marital status, education level, occupation, place of residence, family history, type of cancer and type of treatment ($p>0.05$; Table 1).

At the baseline, the fatigue severity of the experimental group was significantly higher than the control group ($p<0.05$). In order to eliminate the effect of this inconsistency, the fatigue severity variable in the pre-test was considered as a covariance.

Immediately after the intervention, the fatigue severity of the experimental group was significantly lower than that of the control group, but 3 months after the intervention, the fatigue severity of the control group was significantly lower than that of the control group, which were statistically significant in intergroup comparison (Table 2).

In the experimental group, the fatigue severity of cancer patients under chemotherapy, immediately and 3 months after the end of the intervention was significantly lower than the baseline (11.4 and 12.8, respectively). Although fatigue severity in the follow-up followed a decreasing trend compared with the post-test with 1.5 difference score, but this difference was not statistically significant. In the control group, the fatigue severity of cancer patients under chemotherapy immediately after the end of the intervention, compared with the baseline, with a 2.2 difference score, apparently showed a decreasing trend, but this difference was not statistically significant. Also, in the control group, the fatigue severity of cancer patients under chemotherapy 3 months after the end of the intervention was significantly lower than the baseline and immediately after the intervention, with 14.3 and 12.1 scores, respectively (Table 3).

Table 1) The absolute and relative frequency of the demographic variables of the Patients in the experimental (24 persons) and control (24 persons) groups at the baseline (the numbers in parentheses are percentages)

Demographic qualitative variables	Experimental group	Control group
Gender		
Male	3 (12.5)	10 (41.7)
Female	21 (87.5)	14 (58.3)
Age group		
Up to 45 years (adults)	5 (20.8)	1 (4.2)
46 years and older (middle age and elderly)	19 (79.2)	23 (95.8)
Marital status		
Single	5 (20.8)	2 (8.3)
Married	19 (79.2)	22 (91.7)
Education		
Illiterate and elementary	7 (29.2)	14 (58.4)
Secondary and high school	5 (20.8)	5 (20.8)
Diploma and above	12 (50.0)	5 (20.8)
Occupation		
Unemployed	4 (16.7)	6 (25.0)
Non-governmental	3 (12.5)	4 (16.7)
Employee	5 (20.8)	2 (8.3)
Housewife	12 (50.0)	12 (50.0)
Place of residence		
Urban	24 (100)	20 (83.3)
Rural	0	4 (16.7)
Family history		
Yes	9 (37.5)	10 (41.7)
No	15 (62.5)	14 (58.3)
Type of cancer		
Uterus, ovary and breast cancer	19 (79.2)	17 (70.8)
Gastrointestinal and skin cancer	5 (28.8)	7 (29.2)
Treatment type		
Only chemotherapy	8 (33.3)	15 (62.5)
Chemotherapy plus other therapies	16 (66.7)	9 (37.5)

Table 2) Intergroup comparison of fatigue severity among cancer patients under chemotherapy

Stages	Experimental group	Control group	F	P value
Baseline	54.8±9.1	49.0±9.8	4.5	0.2
Immediately after the intervention	43.4±6.9	46.8±12.9		
3 months after the intervention	41.9±4.8	34.7±10.1		

Table 3) Paired comparison of mean scores in different times using Bonferroni test in the experimental and control groups

Time	Mean difference	P value
Experimental group		
T1-T2	-11.4	0.0001
T1-T3	-12.8	0.0001
T2-T3	-1.5	1
Control group		
T1-T2	-2.2	1
T1-T3	-14.3	0.0001
T2-T3	-12.1	0.1

T1: At baseline; T2: Immediately after the intervention; T3: 3 months after the intervention

Discussion

According to the results, 5A self-management model decreased fatigue severity of patients with cancer under chemotherapy in the intervention group, however this independent variable could not provide a distinction between the fatigue severity of the intervention group and the control group, which indicates the effectiveness of this intervention.

The most similar findings to this study are the results of Yates *et al.* [25], which indicated that educational intervention for fatigue management on women with breast cancer under chemotherapy has reduced fatigue severity, but these changes were not significantly different with that of the control group [25].

Also, the results of research by Du *et al.* [26], Rietberg *et al.* [27], Forjuoh *et al.* [28], Purcell *et al.* [29], Björneklett *et al.* [30], Balk *et al.* [31], Dodd *et al.* [32], Husebø *et al.* [33] and Saarto *et al.* [34] are consistent with the findings of the present study indicating that there is no significant reduction in the fatigue severity due to intervention based on 5A self-management model.

Contrary to these consistent studies, the results of Ahmadi *et al.* [18], Chan *et al.* [35], Kwekkeboom *et al.* [36], Yesilbalkan *et al.* [37] and Mulligan e*t al.* [38] did not support the results of this study and the results of these studies indicate that fatigue decreased significantly after intervention based on self-management model as a research intervention.

Although the inconsistency of the results of the present study with these studies can be due to the difference in research interventions, the duration of the intervention, the research community and the data collection tool, but the severe reduction in fatigue severity of the control group 3 months after the intervention compared with the experimental group in the present study, significantly decreased the fatigue severity of cancer patients under chemotherapy due to the effect of the independent studied variable.

A significant decrease in fatigue severity in the control group compared with the experimental group 3 months after the intervention, in addition to the probability of sampling error, can be attributed to the fact that the effects of fatigue-related interventions is associated with the stage of cancer, the experience of the treatment process and the psychological states and also specific states can also be effective in reducing the severity of cancer-related fatigue at different times in the cancer treatment process [39].

In this regard, Farajalahi *et al.* believe that the severity of fatigue has been correlated with the number of treatment cycles, meanwhile, cancer patients under chemotherapy in a chemotherapy cycle also experience varying degrees of fatigue, which is the highest on the fifth day of the treatment cycle [40].

The above mentioned cases, in addition to providing a good justification for the findings of this study, make the researchers aware of the most obvious weak point of the present study, including the lack of attention to the number and process of chemotherapy cycles. Accordingly, it is recommended that researchers in their future studies on the fatigue severity of cancer patients under chemotherapy consider the coincidence of the number of treatment cycles and the time taken to measure fatigue.

One of the most important uncontrollable limitations of the present study is that, due to ethical considerations, the samples should not be deprived of routine treatments and emergency interventions; on the other hand, the critical and variable status of these patients may require that they receive special medications or interventions during the intervention, which may affect the measured severity of their fatigue.

It is suggested that in future studies, by conducting more extensive studies, the studies be designed more accurately and more precisely, to increase differentiation between the values of dependent variables, so that the differences can be significantly differentiated.

Conclusion

5A self-management model decreases fatigue severity of patients with cancer under chemotherapy in the intervention group, however this independent variable can not provide a distinction between the fatigue severity of the intervention group and the control group, which indicates the effectiveness of this intervention.

Acknowledgements

This study was extracted from a master's degree thesis of the Faculty of Nursing of Yasuj University of Medical Sciences, which was funded by this university.

Ethical permissions

This study was approved by the Yasuj University of Medical Sciences Research Ethics Committee (Ethics code: IR.YUMS.REC.1395.83) and registered on the Iranian Registry of Clinical Trials (IRCT2016080829266N1). We would like to thank the efforts of the staff of the Faculty of Nursing and Vice-Chancellor for Research and Technology of Yasuj University of Medical Sciences, Iran, Nurses of the Chemotherapy Center of Shahid Motahari Clinic of Shiraz, the subjects, including patients under chemotherapy and their families as well as all who helped in this study.

Conflicts of interests

None declared.

Authors' contribution

Marjan Roozitalab (first author), writing introduction/main researcher (30%); Nazafarin

Hosseini (second author), methodologist/writing discussion (30%); Mehrdad Vossoughi (third author), writing introduction/assistant researcher (10%); Mohammad Zoladl (fourth author), methodologist/statistical analyst/ writing discussion (30%).

Funding/Support

Vice-Chancellor of Research and Technology of Yasuj University of Medical Sciences funded this research.

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