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The Effect of Pain Management Training on the Severity of Pain in Patients with Cancer: A Clinical Trial Study

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Abstract

Background: Pain is the most common and frustrating symptom of cancer. Despite the availability of different guidelines for its management, controlling pain is still not possible.
Objectives: The current study aimed at evaluating the effect of pain management education on the severity of pain in patients with cancer.
Methods: The current clinical trial (IRCT201403122226N14) was conducted during the year 2014, in association with two hospitals affiliated to Arak University of Medical Sciences in Iran. In this study, 98 patients with cancer were designated to either the intervention or control group. The intervention included six educational sessions and a training manual. The severity of pain in patients was assessed prior to the intervention, and at three and six weeks after the intervention.
Results: Data showed that 55.1% of the patients were male and 65.3% were married. The majority (33.67%) were aged 18 to 30 years old. At the beginning of the study, the study population was homogenous for the demographic variables and severity of pain ($P = 0.871$). The mean (SD) score of pain severity in the intervention group before, at three, and six weeks after the intervention was 30.18 (8.18), 17.46.18 (11.10), and 16.51 (10.83), respectively ($P < 0.001$). The mean (SD) score of pain severity in the control group before, at three, and six weeks after the intervention was 30.44 (8.007), and 75.7 (10.9), 30.08 (8.37) and 29.95(8.49) respectively ($P = 0.955$). After the intervention, a significant difference was observed in the severity of pain between the groups ($P < 0.001$).
Conclusions: The results showed that pain management training could reduce the severity of pain in patients with cancer. Therefore pain management training could be designed for patients with cancer in order to promote their quality of life.

Keywords: Cancer, Pain Management, Quality of Life, Severity of Pain, Training, Visual Analogues Scale

1. Background

Cancer is a major public health problem worldwide (1). According to estimations of the GLOBOCAN (2), approximately 14.1 million newly diagnosed cancer cases and 8.2 million deaths due to cancer occurred globally. In addition, cancer is the third leading cause of death in Iran, with breast, colorectal, bladder, gastric, and prostate cancers being the most common types of cancer among the Iranian population. Furthermore, among all types of cancer, gastrointestinal and breast cancers had the highest prevalence and were the leading cause of death due to cancer (3). Pain is the most common, frustrating symptom of cancer, with more than half of the patients with cancer experiencing pain due to the nature of the disease and therapeutic practices (4-6). More than one-third of these cases have moderate to severe degree of pain (7). Patients with uncontrolled pain may also experience high levels of depression and anxiety, which can affect their daily personal functioning, movement, socialization, sleeping, and enjoyment of life, and impose a high economic burden (4). Furthermore, according to patients with cancer, pain can also inhibit their focus and thinking, which affects their daily personal affairs (8). Thus, given its effect on personal functioning and Quality of Life (QOL), adequate assessment and management of pain are vital for patients with cancer (9). The management of pain, via pharmacological and non-pharmacological methods, is the most important therapeutic practice in cancer (10-12). However, currently used protocols to manage pain have proven to be unsatisfactory

for most patients (6). One of the main obstacles to control pain is insufficient knowledge about pain and its management (13, 14). Most patients deprive themselves of pain relief due to misconceptions about sedatives and their side effects and do not adhere to the regular treatments (15). In addition, patients and their families often fear addiction to opioids (16). Furthermore, most patients are unaware of non-pharmacological pain management methods (17).

Thus, despite pain management guidelines and strategies that are currently available to improve patients' health status, cancer pain remains untreated (18).

Studies have demonstrated that training increases the level of knowledge about pain management in patients with cancer and enhances positivity in their daily life and personal functioning (4, 13, 19). Other studies have also noted the positive effects of training on the level of knowledge, self-care, and self-efficacy in patients (19-21). However, Kravitz et al. demonstrated that although training temporarily reduced pain-associated complications in patients, it had no effect on the severity of pain and the reduction of pain outcomes (22).

Currently, pain management, as one of the most important components of palliative care, is very important in cancer patients. Pain management training can be useful to patients and improve their quality of life. One of the important tasks of nurses, as a member of the care team, is to control the pain of patients. By controlling and managing the pain of cancer patients, they can improve the patient's well-being and reduce their suffering. Despite the importance of this issue, there are a few studies focused on this phenomenon in patients with cancer. Also, there are no studies in this field in Iran to determine the effect of pain training program on the severity of pain in these patients.

2. Objectives

The current study aimed at evaluating the effect of pain management training on the severity of pain in patients with cancer.

3. Methods

3.1. Study Design and Participants

The current clinical trial, registered in the Iranian Registry for Clinical Trials (Reg. No. IRCT201403122226N14) was conducted after obtaining approval of the Ethics Committee of Tehran University of Medical Sciences, Tehran, Iran (93-01-28-25022). The study population included patients with cancer, who were referred to two governmental and referral hospitals affiliated to Arak University of Medical Sciences, during year 2014.

The inclusion criteria included the following: An age range of 18 to 65 years old, confirmation of cancer diagnosis by a physician, a pain score of $\geq$ 4, based on the Visual Analogue Scale (VAS), and the ability to talk and understand others. The exclusion criteria were as follows, undergoing invasive pain management, such as subcutaneous or intravenous injection of opiate, unwillingness to cooperate in the study, and not attending the intervention sessions.

3.2. Sample Size

In the present study, the sample size was determined by the power software and based on the data extracted from the results of a study conducted by Oldenmenger et al. (13). With a significance level of 0.05, confidence interval of 95%, and power of 80%, as well as 10% loss of follow-up, the sample size was estimated as 49 patients in each group. There were no missing values.

$$\begin{aligned} n &= \frac{\left(z_{1-\frac{\alpha}{2}} + z_{1-\beta}\right)^2 \left(S_1^2 + S_2^2\right)}{\left(\bar{X}_1 - \bar{X}_2\right)^2} \\ &= \frac{(1/96 + 0/84)^2 \left(13^2 + 10^2\right)}{(71 - 64)^2} \\ &= 43/4 \\ &\cong 44 \end{aligned} \quad (1)$$

3.3. Sampling and Random Allocation

The patients were first required to complete a demographic questionnaire to identify eligible participants, who met the inclusion criteria. Then objectives of the study were explained to eligible patients, who provided written informed consent and were enrolled in the study. The convenience sampling method was used in the current study to select participants from hospitalized patients. The selected patients were allocated to either the intervention or control group, using block randomization, with block sizes of four. The blocks were arranged using computer-generated random numbers. For study blindness, a person as a researcher's assistance placed the patients in the intervention and control groups, according to the list of four blocks. Finally, the statistician, who was not aware of the groups, did the statistical analysis.

Table 1. Educational Headlines of the Training Sessions

Session	Educational Contents
1	Getting familiar with other classmates, aims and objectives, general cancer overview
2	Cancer pain and its effect on different aspects of life, patients and families' barriers to cancer pain control
3	Pharmacological methods for cancer pain management, their side-effects, and management strategies
4	Non-pharmacological pain-management methods, including cognitive-behavioral (self-talking, imagination, relaxation, etc.), distraction or entertainment, music therapy, bathing, etc.
5	Following the previous session on non-pharmacological pain-management methods and practicing some of them
6	Answering patients, discussion, evaluation of knowledge, providing the training manual

3.4. Interventions

In the intervention group, training sessions were held for each patient for a period of three weeks. Each session lasted for 20 minutes. The VAS pain score was completed at three-time points by each participant, i.e., at the beginning of the study, and at three and six weeks after the intervention. The control group received routine medical care. The intervention included six 20-minute sessions, which was conducted individually at the hospital. The training sessions provided general information about cancer, cancer pain and its impact on different aspects of life, personal and familial barriers to control cancer pain, pharmacological treatments and their outcomes, and non-pharmacological pain management methods, including cognitive-behavioral, distraction or entertainment, music therapy, relaxation, massage, bathing, etc. (Table 1). Palliative care specialists provided answers to the patients' questions and discussions. At the end of the training sessions, a training manual, including the educational information, was given to each participant.

3.5. Data Collection Tools

Tools for data collection in this study included:

1) Socio-demographic questionnaire (including age, gender, marital status, educational level and occupation, monthly income, etc.).

2) The VAS pain score was used to assess the severity of pain, which is a standard, validated, and reliable instrument for measuring the severity of pain in patients (15). The VAS pain score is a ruler graded from 0 to 10, which is scored based on the patients' comments. It is used by patients to assess the level of pain. The instrument classifies pain based on the given scores, which are categorized as follows: No pain (zero score), mild pain (one to three), moderate pain (four to six), severe pain (seven to nine), and the most imaginable pain (ten). The validity and reliability of this tool were confirmed in many studies. In the study, the correlation coefficient was confirmed by r = 0.86 (15-18).

3.6. Ethical Considerations

The objectives of the study were explained to the participants to comply with ethical considerations. All the participants signed the written informed consent prior to enrolment. The patients were free to withdraw from the study at any time and stage. At the end of the study, the training manual provided to the intervention group was also given to the participants of the control group.

3.7. Data Analysis

Data were analyzed using SPSS version 16. Normal distribution of the quantitative data was confirmed using the Kolmogorov-Smirnov test. Descriptive statistics, including frequency, percentage, mean, and standard deviation, were used to define the pain score of patients. For comparing the pain score, the *t*-test was used before the intervention. Also, the chi-square, post hoc, independent *t*-test, paired *t*-test, and repeated measures Analysis of Variance (ANOVA) was performed. $P < 0.05$ was considered significant.

4. Results

A total of 98 patients with cancer were evaluated in the current study; most of them (33.67%) were aged 18 to 30 years old. 55.1% of the patients were male, and 65.3% were married. The majority (30.6%) held a high school diploma. The most common diagnosis was gastrointestinal cancer (22.45%), while lung cancer, which occurred in 8.16% of the patients, had the lowest prevalence. The most extended duration of cancer was less than five years, which occurred in 83.7% of the patients. The groups of the current study were homogenous regarding the demographic variables (Table 2).

At the beginning of the study, 18.37%, 45.2%, and 35.71% of patients reported the most reasonable degree of pain, severe pain, and moderate pain, respectively. Although there were no significant differences between groups regarding the severity of pain prior to the intervention ($P = 0.871$), the differences were significant at three and six weeks after the intervention ($P < 0.001$).

Compared to the start of the study, the severity of pain was reduced in the intervention group, by the end of weeks three and six. However, there were no significant changes in pain scores of the control group, between the three-time points (i.e., beginning of the study and at three and six weeks after the intervention) ($P < 0.001$).

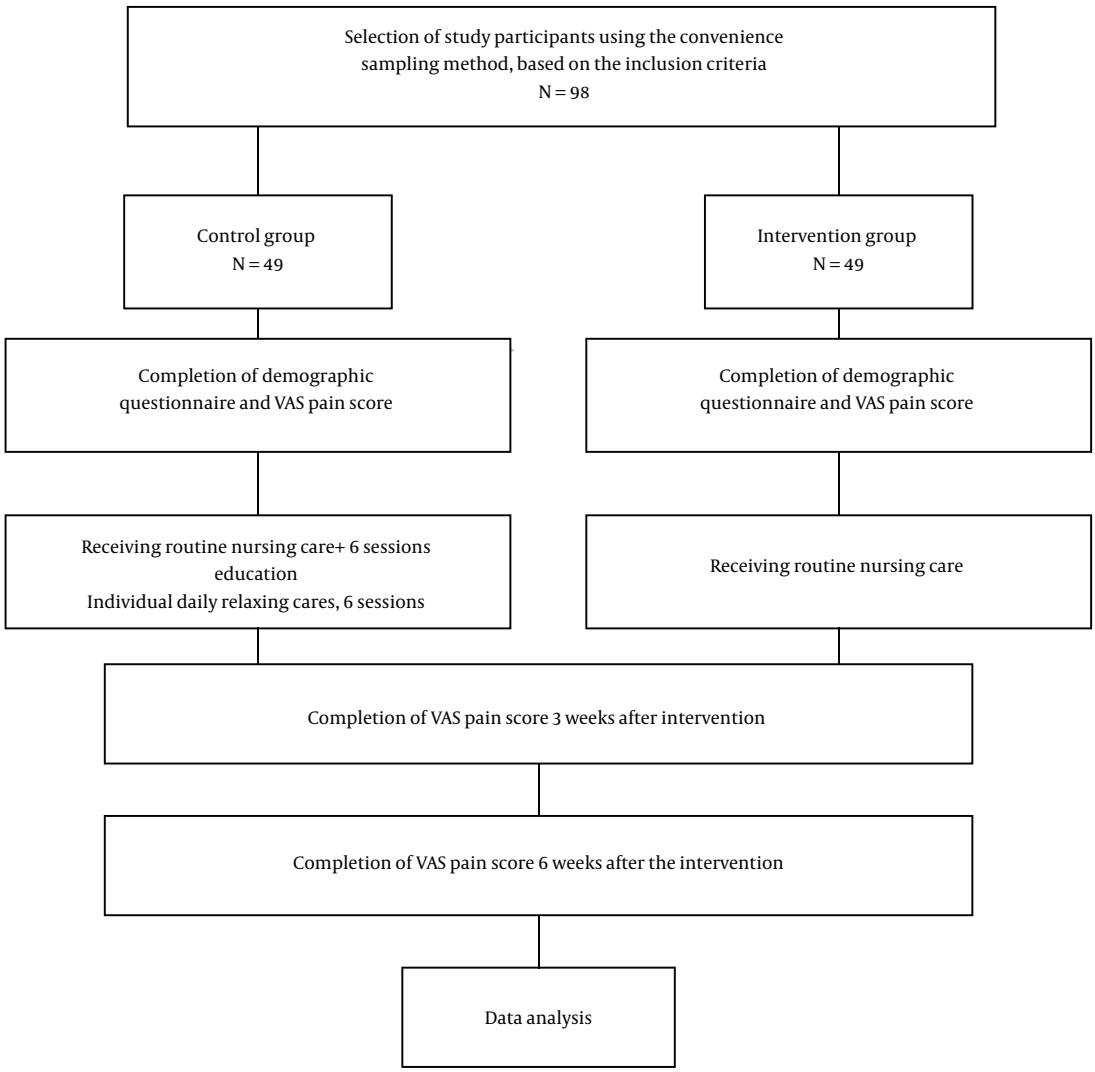

Figure 1. Study procedure workflow

In the intervention group, although the reduction in the severity of pain between the beginning of the study, and at three and six weeks after the intervention ($P < 0.001$) was significant, the difference in the severity of pain was not significant between week three and week six after the intervention ($P = 0.99$) (Table 3).

5. Discussion

A total of 98 patients with cancer were evaluated in the current study, with the majority experiencing high levels of pain. Most of the participants, however, had insufficient knowledge about pain management and self-relaxation techniques. The current study showed that such patients needed more support and education in this regard. The results of the current study corroborated with previous studies (20-22).

At the beginning of the current study, 18.37%, 45.9%, and 37.1% of the patients reported the highest level of pain, severe pain, and moderate pain, respectively. Garud et al. also reported that the level of pain was moderate to severe in one-third of such patients (7). In addition, a review by van den Beuken-van Everdingen et al. of 52 studies, revealed that more than 35% of the patients experienced moderate to severe level of pain (pain score $\geq$ 5 based on the VAS) (8). Furthermore, Rustoen et al. demonstrated that the prevalence of uncontrolled pain among patients with cancer ranged from 20% to 64% (19).

Table 2. Demographic Characteristics of Participants in This Study[a]

	Intervention Group	Control Group	P Value[b]
Age, y			0.913
18 - 30	17 (34.7)	16 (32.7)	
31 - 42	14 (28.6)	13 (26.5)	
43 - 54	10 (20.4)	13 (26.5)	
55 - 66	8 (16.3)	7 (14.3)	
Gender			0.420
Male	26 (53.1)	28 (57.1)	
Female	23 (46.9)	21 (42.9)	
Marital status			0.671
Single	16 (32.7)	18 (36.7)	
Married	33 (67.3)	31 (63.3)	
Educational level			0.953
High school	9 (18.4)	29 (59.2)	
Diploma	16 (32.7)	14 (28.6)	
Academic	5 (10.2)	6 (12.2)	
Cancer history in the family			0.616
Yes	9 (18.4)	11 (22.4)	
No	40 (81.6)	38 (77.6)	

[a] Values are expressed as frequency (%).
[b] $P < 0.05\%$ was considered significant.

The level of pain did not significantly differ between the groups prior to the intervention ($P = 0.871$); however, there were significant differences between the groups at three and six weeks after the intervention ($P < 0.001$).

In comparison to the level of pain of the control group and prior to the intervention, pain management training significantly reduced the level of pain in the intervention group at three and six weeks after the intervention. Thus, the positive effects of intervention lasted for at least six weeks after the intervention. A review by Adam et al. of eight systematic evaluations and 34 randomized controlled clinical trials revealed that targeted interventions could slightly and moderately reduce the level of pain in patients with cancer. The studies reviewed in the current study included at least one of the following seven items: Promotion of knowledge about the nature of cancer pain, helping patients communicate their pain, pain assessment, improvement of the drug prescription, coping with barriers to the adherence to medication, training strategies of non-pharmacological pain management, and improvement by reassessments. The studies selected by Adam et al. however, only incorporated four of the seven items, namely the promotion of knowledge about the nature of pain, improvement of the drug prescription, coping with barriers to medication adherence, and training strategies of non-pharmacological pain management (23). Oldenmenger et al. demonstrated that training programs could significantly reduce the level of pain. The training evaluated in their study included weekly education session on pain and its side-effects. After the intervention, patients showed a tendency to adhere to the prescription of sedatives (13). The severity of pain in the intervention group was lower than that of the control group in the current study. A review conducted by Cummings et al. of 26 studies on healthcare providers, patients, and their families, out of which 17 studies focused on patients, reported reduced pain levels following the training intervention. These studies also indicated positive behavioral changes in patients following the implementation of pain control strategies, such as significant improvement in self-care behavior, including the administration of proper doses of medicines, improvement in perceived pain control in patients, and adherence to the therapeutic regimen, pain control methods, and administration of sedative opiates. The review study also showed a significant relationship between the level of pain and pain management training, indicating that proper education could reduce the level of pain in patients (4). A study by Kravitz et al. demonstrated a significant improvement in the control of pain outcomes after two weeks of pain management training. However, the training had no effect on the severity of pain at the six- and twelve-week follow-up. Hence, they reported that pain management training did not affect on the improvement of pain outcomes (22). A systematic review and meta-analysis conducted by Bennett et al. however, demonstrated that pain management training guided patients towards pain management, finally enabling them to better manage cancer. The intervention in most of the studies included 15 to 60 minutes of face-to-face coaching sessions, with a training manual for the participants. The training interventions were conducted by nurses in seven studies, while the positions of the researchers were unclear in the other studies. The increase in the level of knowledge improved pain control in patients in all studies conducted in this regard, except one. The results of the latter, however, showed that patient-oriented training interventions could improve the level of knowledge and attitude towards pain and reduce its severity in patients with cancer. Thus, increased knowledge and an improvement in attitude enabled patients to actively engage in pain management and may have even influenced patients to better report pain and its outcomes to healthcare providers, improve the sense of pain control, and reduce anxiety (24). The differences among the results of studies can be attributed to differences in cultural and educational contents.

Although there was a significant difference in the

Table 3. Comparison of Mean Pain Scores of Patients with Cancer in the Intervention and Control Groups[a]

Severity of Pain	Intervention Group	Control Group	P Value
Before education	30.18 ± 8.18	30.44 ± 8.007	0.871
Three weeks after education	17.46.18 ± 11.10	30.08 ± 8.37	< 0.001
Six weeks after education	16.51 ± 10.83	29.95 ± 8.49	< 0.001
P value	< 0.001	0.955	

[a]Values are expressed as mean ± SD.

severity of pain in the interventional group, between the start of the study, and at three and six weeks after ($P < 0.001$), the difference in the pain level was insignificant between weeks three and six ($P = 0.99$) (Table 2).

Educational interventions usually improve knowledge and skills, and modify the attitude towards pain control, which consequently results in pain relief (4). Lack of knowledge, misconceptions about self-management of pain, and obstacles to implement the method, inhibit the effectiveness of the training method in patients with cancer (14). Eliminating these obstacles and planning proper educational programs can improve patients' knowledge and motivate them to engage in self-care practices (25). The results of a study by Jahn et al. on the effect of pain management training for patients by nurses, emphasizing on knowledge, activities, and attitude of patients towards pain management showed that the training program could significantly remove the barriers to pain management for patients. In addition, patients showed improvement in adherence to therapeutic regimens (24). The current study showed a reduction of medium and severe levels of pain, following the nursing intervention for self-management of pain in patients with cancer (26). The difficulty in following up patients at three and six weeks after the intervention was one of the limitations of the current study.

5.1. Conclusion

Results of the current study indicated positive and significant effects of pain management training on the level of pain in patients with cancer. In fact, patients, who underwent pain management education experienced lower levels of pain and the level of their pain was significantly reduced. It is suggested that conducting pain management programs routinely for patients with cancer will be beneficial.

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Footnotes

Clinical Trial Registration: IRCT201403122226N14.

Conflict of Interests: There were no conflicts of interest.

Ethical Considerations: Ethical Code: 93-01-28-25022.

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