

The effect of mobile-based patient education on nausea and vomiting of patients undergoing chemotherapy.

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Abstract

Introduction: Nausea and vomiting related to chemotherapy are among the most severe side effects and are one of the most important concerns of patients with cancer. Training patients under chemotherapy is an inseparable part of nursing care. This study has been conducted aiming to determine the effect of mobile-based education on nausea and vomiting in patients undergoing chemotherapy.

Methods: In this open-label clinical trial, 50 cancer patients were enrolled according to entry criteria. The subjects were divided into case and control groups by random block method in senary blocks. Patients of both groups were in the same conditions in terms of age, type of cancer, severity of nausea and vomiting, chemotherapy regimen (cisplatin or cyclophosphamide) and anti-vomiting regimen (ketril plus dexamethasone). The control group received only routine training, and the case group received educational content in the form of mobile software. In order to measure the effect of intervention, Visual analogue scale (VAS) of nausea and Khavar oncology scale were used. In order to analyze the data, SPSS software version 21 was used.

Results: There was no significant difference between the two groups in terms of demographic characteristics and clinical characteristics. After the intervention, the severity of nausea has decreased in the intervention group, but in the control group, the nausea has been unchanged ($p=0.000$). The mean score of vomiting in the control group was increased and decreased in the intervention group, and this decrease was statistically significant ($p=0.000$).

Conclusion: According to the results of this study, the development of a coherent curriculum by mobile education software by oncology nurses will have a significant effect on controlling the complications of chemotherapy in cancer patients.

Keywords: Cancer, Chemotherapy, Chemotherapy complications, Mobile software.

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Introduction

The second most common cause of death in developed countries is cancer, with a 23% mortality rate [1]. The increase in the incidence of various types of cancer worldwide has been estimated from 12.7 million in 2008 to 22.2 million people by 2030 [2]. In developing countries such as Iran, cancer is the third leading cause of death, with more than 30,000 deaths annually from the Iranian population. It is estimated that more than 70,000 new cases of cancer occur annually in the country [3].

Commonly used conventional cancer treatments include surgery, radiotherapy and chemotherapy [4]. Chemotherapy, unlike the two other therapies, is a systemic method, which leads to serious and numerous side effects, including nausea, vomiting, anxiety, depression and fatigue etc. [5,6].

Nausea and vomiting associated with chemotherapy are among the most severe side effects and are a major concern for cancer patients, with an incidence of between 54%-96%. These two complications cause a lot of problems for patients and

sometimes these problems are so severe that can cause patients to stop continuing the treatment. It also causes physiological disorders, electrolyte imbalances, changes in the immune system, nutritional disturbances, and even esophageal rupture and affects the quality of life and continuing treatment of patients [6-9].

Given that cancer treatment is often done at outpatient clinics today, therefore, many patients should manage the symptoms of illness and side effects of treatment at home. A comprehensive training plan that meets the needs of patients can reduce the incidence of side effects, increase participation in health care programs, reduce health care costs and increase patient autonomy [10].

There are several methods for patient's education that include individual education, group training, education and follow-up care *via* telephone, education in form of community health nurses home-visiting and mobile-based education [11]. Mobile technology is one of the cornerstones of information and communication technology that has come into the field of

education and has been proposed as a mobile-based education. This communication tool has been able to change the traditional way of in-service training and provide a new definition of education. Also, temporally and spatially, the background of learning has paved the way for learners at home, at work, travel, and has removed many limitations and inefficiencies [12]. According to studies which have highlighted the impact of mobile application on the improvement and reduction of complications from cancer, and with regard to the limitations of traditional methods of education such as group training [13-15]. In light of the limited studies of mobile-based education for cancer patients, this study was conducted to apply mobile-based education to reduce the complications of chemotherapy in cancer patients.

Materials and Methods

The present study was a quasi-experimental and open label study, which was conducted in 2016 at the Ahvaz Chronic Disease Care Research Center in Iran. This research was registered in the Iranian clinical trials registration system with the registration number of IRCT 2016100430128 N1. After approving the design and approval of the ethics committee of the Jundishapur University of Medical Sciences in Ahvaz, the samples were taken with the consent of the Shafa oncology hospital in Ahvaz.

The statistical population of this study was cancer patients who were undergoing chemotherapy and had a medical record in the chemo unit at the Shafa Hospital of Ahwaz. At first, the patient records were reviewed and a list of eligible patients was obtained. After a general description of the study and obtaining written informed consent from the patients to participate in the study, ultimately, out of the 80 eligible patients, 50 patients were enrolled in the study, using a goal-oriented sampling method in the form of block random method and using the senary blocks, they were assigned to two groups of case (n=25) and control (n=25). Inclusion requirements include willingness to participate in a research project and signing a written consent form, confirmation of diagnosis of cancer by a specialist physician and being on the chemo list, all patients have received at least one chemotherapy course, have a mobile phone with a software applicability, have the ability to read, or have a literate family member, complain of nausea and vomiting due to chemotherapy, have cisplatin or cyclophosphamide in the chemotherapy protocol. In addition, exclusion criteria includes patient's dissatisfaction with the continuation of the study, any other sickness or condition that causes nausea and vomiting, such as bowel obstruction, etc., the use of other complementary therapies or herbal therapies to control nausea and vomiting, ill patients who cannot answer questions, coincidence of chemotherapy with radiotherapy.

The researcher introduced himself to the research units and explained the purpose of his research to them and attracted their cooperation. Participants were told that they can leave the research whenever they want to, and that their absence or participation does not affect their usual treatment. Patients' phone numbers and addresses were recorded for subsequent

follow-up. The demographic information questionnaire (age, sex, marital status, degree of education, chemotherapy protocol, chemotherapy routine and duration of the disease) was completed by the research samples and by the researcher using medical records of patients.

To measure the severity of vomiting, the Khavar Oncology scale was used, this is a standard scale [16]. According to this scale, 1-2 vomiting per day (mild vomiting), 3-5 times (vomiting with a moderate degree) and more than 5 times (vomiting with severe degree) were considered [17].

In order to determine the severity of nausea, a Visual Analogue Scale (VAS) was used, the reliability of this instrument was confirmed by Cronbach's alpha coefficient of 0.948 [18]. In this way, the patient was asked to rate their nausea on a 10 cm vertical ruler. In the ranking of the ruler, the degree less than 3.5 was considered as (mild nausea), 3.5-7 as (moderate nausea) and more than 7 as (severe nausea) [19].

The above scales were completed in both groups before intervention. In the intervention group, the mobile application program provided on the cell phone was displayed to the patient and its use and its applications were expressed by the researcher. Then the application was sent *via* Bluetooth on the participant's phone and then installed. After installing the program, its function was controlled on the patient's phone and, by cooperating with the patient, was examined for its use and application. Participants were asked to contact the researcher at any time during the intervention period in case of problems with the program work or have a question. In addition, there was no intervention in the control group and the patients in this group were only trained by routine physicians and nurses.

The provided software includes the introduction of cancer disease, chemotherapy and its complications, important recommendations for reducing nausea and vomiting and how to start a diet after vomiting, as well as two educational clips that explained the complications of chemotherapy and how to cope with it and an uncanny music for relaxing body. After a month, the end of the intervention, all the participants in the study (control and intervention groups) completed the nausea severity scale and Khavar oncology scale. The results were recorded and finally, in order to analyze the data, in addition to calculating Mean and standard deviation of chi-square, independent t-test, paired t-test, Fisher's exact test and Wilcoxon Signed Ranks Tests with SPSS-21 software were used.

Results

In this study, 50 patients with cancer undergoing chemotherapy who had all the criteria to be included in the study formed the samples of this study. Individual information and clinical characteristics of both groups included age, sex, education, duration of onset of illness, duration of chemotherapy and diagnosis as presented in Tables 1 and 2. Statistical tests indicate that the two groups are homogeneous in terms of these variables. According to paired t-test, the frequency of vomiting in the intervention group had a significant difference before

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and after the intervention (Table 3). According to Fisher exact test, the severity of nausea is significant in the two groups before and after the intervention (Table 4). According to chi-square test, the results obtained after intervention in terms of severity of nausea have been significantly different in the two

groups (Table 5). To compare the severity of nausea, there is a significant difference between the two groups of control and intervention before and after the intervention according to the Wilcoxon Signed Ranks Tests (Table 6).

Table 1. Demographic data by intervention and control group and Chi-square test for homogeneity of demographic variables in intervention and control groups.

| Demographic data | | Intervention | | Control | | Total | | Chi-square test for homogeneity of two groups | |
|------------------|-------------------------|--------------|---------|---------|---------|--------|---------|---|-------------|
| | | Number | Percent | Number | Percent | Number | Percent | P-value | Test result |
| Sex | Women | 16 | 64 | 16 | 64 | 32 | 64 | 1 | Homogeneous |
| | Men | 9 | 36 | 9 | 36 | 18 | 36 | | |
| Education | Illiterate | 3 | 12 | 4 | 16 | 7 | 14 | 0.975 | Homogeneous |
| | Elementary | 4 | 16 | 3 | 12 | 7 | 14 | | |
| | Middle school education | 4 | 16 | 5 | 20 | 9 | 18 | | |
| | High school education | 6 | 24 | 5 | 20 | 11 | 22 | | |
| | Academic education | 8 | 32 | 8 | 32 | 16 | 32 | | |
| Diagnosis | Breast cancer | 9 | 36 | 9 | 36 | 18 | 36 | 1 | Homogeneous |
| | Gastric cancer | 3 | 12 | 2 | 8 | 5 | 10 | | |
| | Lung cancer | 2 | 8 | 2 | 8 | 4 | 8 | | |
| | Hodgkin's lymphoma | 2 | 8 | 2 | 8 | 4 | 8 | | |
| | Ovarian cancer | 3 | 12 | 3 | 12 | 6 | 12 | | |
| | Esophageal cancer | 1 | 4 | 1 | 4 | 2 | 4 | | |
| | Testical cancer | 2 | 8 | 2 | 8 | 4 | 8 | | |
| | Bladder cancer | 2 | 8 | 3 | 12 | 5 | 10 | | |
| | Bone cancer | 1 | 4 | 1 | 4 | 2 | 4 | | |

Table 2. Homogeneity of the underlying and medical characteristics of both intervention and control groups at the beginning of the study and before intervention.

| Group | Intervention | | Control | | Total | | t-test for homogeneity of two groups | | | |
|--------------------------------|--------------|----------------|---------|----------------|-------|----------------|--------------------------------------|----|---------|-------------|
| | Mean | Std. Deviation | Mean | Std. Deviation | Mean | Std. Deviation | t | df | p-value | Test result |
| Age | 43.7 | 9.95 | 44.56 | 9.52 | 44.16 | 9.65 | -0.29 | 48 | 0.773 | Homogeneous |
| Chemotherapy the starting time | 1.52 | 0.6 | 1.46 | 0.54 | 0.49 | 0.57 | 0.371 | 48 | 0.712 | Homogeneous |
| Chemotherapy turn | 2.6 | 0.81 | 2.68 | 0.9 | 1.64 | 0.85 | -0.329 | 48 | 0.743 | Homogeneous |

Table 3. Comparison of the number of vomiting in the intervention and control groups before and after the intervention.

| Frequency of vomiting | Intervention group | | Control group | | P-value independent t-test |
|-----------------------|--------------------|----------------|---------------|----------------|----------------------------|
| | Mean | Std. deviation | Mean | Std. deviation | |
| Before intervention | 1.6 | 1.77 | 1.64 | 1.84 | 0.938 |
| After intervention | 0.84 | 1.37 | 2.48 | 2.16 | 0.002 |
| P-value paired t-test | 0.003 | | 0.01 | | |

| | | | | | |
|--------------------------------|-------|-------|------|------|---|
| Difference of before and after | -0.76 | 1.164 | 0.84 | 1.49 | 0 |
|--------------------------------|-------|-------|------|------|---|

Table 4. Comparison of severity of nausea in the intervention and control groups before intervention according to Fisher's exact test.

| Group | Intervention | | Control | | p-value |
|----------------|--------------|---------|-----------|---------|---------|
| | Frequency | Percent | Frequency | Percent | |
| Without nausea | 1 | 4 | 2 | 8 | 0.556 |
| Mild | 9 | 36 | 7 | 28 | |
| Moderate | 10 | 40 | 11 | 44 | |
| Severe | 5 | 20 | 5 | 20 | |

Table 5. Comparison of severity of nausea in the intervention and control groups after the intervention using Chi-square test.

| Group | Intervention | | Control | | p-value | |
|----------------------|--------------|---------|-----------|---------|---------|---|
| | Frequency | Percent | Frequency | Percent | | |
| Difference of nausea | -1 | 22 | 88 | 2 | 8 | 0 |
| | 0 | 2 | 8 | 17 | 68 | |
| | 1 | 1 | 4 | 6 | 24 | |

Table 6. Paired comparison of severity of nausea in the intervention and control groups before and after the intervention according to Wilcoxon test.

| Frequency of nausea | Intervention group | | | Control group | | |
|------------------------------|---------------------|---------------------|---------|---------------------|---------------------|---------|
| | Negative difference | Positive difference | P-value | Negative difference | Positive difference | P-value |
| Differences before and after | 1 | 22 | 0 | 2 | 6 | 0.289 |

The results of the above table show that the number of women in both groups is higher than that of men and this ratio is homogeneous in both groups. A total of 64 percent has been women and 36 percent has been men (Sig=1.000). Most of the subjects have had academic education (32%) and in the next stage, they have had high school education (22%), and this level has been homogeneous in both groups (Sig=0.975). The diagnosis of the type of cancer in most of the subjects has been about breast (36%). The ratio of diagnosis has been homogeneous in two groups (Sig=1.000).

According to the results of the above table, the mean age in the intervention group has been 43.7 and 44.56 in the control group, which is homogeneous in the two groups (0.773). Chemotherapy the starting time before the intervention in the intervention group is 1.5 and it is 1.46 in the control group, which is homogeneous in the two groups (0.712). Chemotherapy turn is also homogeneous in both groups (0.743). The above table shows that according to the independent t-test, at the beginning of the study and before the training, both groups have been homogeneous and equal in terms of the frequency of vomiting (P-value=0.938). But after the intervention, both groups have a statistical significant difference (P-value=0.002).

By examining the result of the changes, it is observed that the intervention group decreased 0.76 units of vomiting frequency, but the control group had an increase of 0.84 units, so these two values are statistically significant with each other (P-

value=0.000). The results of paired t-test also confirm that the changes in the intervention group has been significant (P-value=0.003) and there has been a significant difference in the control group before and after intervention, but regarding an increase in vomiting (P-value=0.010).

According to the above cross-sectional table and Fisher's exact test (due to the fact that houses with fewer than 5 abundances were used from Fisher exact precision), there is a significant relationship between the intervention and control groups and the severity of nausea before intervention (P-value=0.566). In the two intervention groups, most of the samples (40%) in the intervention and (44%) in the control group was moderate in terms of the severity of nausea before the intervention.

According to the above cross-sectional table and the result of qui square test, there is a significant relationship between intervention and control group and nausea difference value (P-value=0.000).

In the intervention group, in most of the samples (88%), the nausea difference before and after the intervention is -1, that is nausea has been decreased for one unit. In the control group, most (68%) of the patients had unchanged nausea.

The table above shows that according to the Wilcoxon Signed Ranks Tests, in the intervention group, nausea has increased in one person after the intervention and decreased in 22 patients and there has been no difference in the rest of the subjects, so this difference is significant (P-value=0.000). In the control

group, nausea has increased in six patients and decreased in 2 patients and has not differed for the rest of the subjects. This difference is not significant in the control group (P-value=0.289).

Discussion

The present study aiming to compare the effect of mobile-based education on nausea and vomiting of patients undergoing chemotherapy is one of the first studies that have been done in the area of mobile software-based education of patients with cancer. According to the results of the present study and comparing means of before the intervention and one month later on 50 patients with cancer undergoing chemotherapy, a significant reduction is observed in scores of vomiting frequency, and severity of nausea. In the group receiving mobile-based education intervention that is statistically significant. However, no significant difference was observed before and after intervention in control group.

The results indicate that education *via* mobile software has had a positive effect on reduction of the side effects resulted from chemotherapy such as nausea and vomiting. Therefore, findings indicate the point that lack of knowledge and awareness of patients can have a direct relationship with severity of nausea and frequency of vomiting, so that after education, patients have experienced less severity of nausea and frequency of vomiting.

In this regard, study of showed that designing educational software to prevent breast cancer along with participation of users led to a significant increase in amount of doing breast self-evaluation task among the users of this software [20].

Results of the present study is aligned with the results of that addressed designing and evaluating education based application on smartphones to take care of children suffering from Cerebral Palsy [21]. The results of this study indicate the positive effect of this method to facilitate learning process to caregivers of children with Cerebral Palsy.

In another review by on the effect of remote nursing (mobile software program) A1c haemoglobin of patients with diabetes type 2, similar results have been obtained. The results have shown that using remote nursing (mobile software) can decrease A1c haemoglobin in patients with diabetes type 2. Aligned with the findings of the present study, it has been shown that using such a technology can be considered as a stimulating and effective tool for both patients and treatment group members in treatment follow-ups [22].

While in a study aimed to compare the effect of both electronic and face-to-face education methods on depression, anxiety, and stress of patients with breast cancer. The results obtained from this study indicate that education by electronic method has created similar results to face-to-face education for patients with breast cancer, and there has not been any significant statistical difference in both mentioned methods to educate these patients [23].

Results of that have addressed and compared traditional, pamphlet and electronic education on reduction of anxiety mean of patients with acute myocardial infarction did not show any significant statistical difference among the three educational methods [24].

In a study done by on determining tablet software application to educate various treatments helping cancer by doctor, it was stated that although this type of education method is positive and statistically significant, due to time limitation, low volume of sample and lack of control group, the researcher recommends to do more research in future to evaluate this effect more and also recommends this type of research to be applied by nursing team and other clinical groups in addition to the doctor to review this type of effect on educating a patient [14].

In addition, in another review by on determining the effect of using mobile software to improve caring women with breast cancer undergoing chemotherapy, the results showed that despite the positive effect of using mobile application to support women against unique challenges of breast cancer and chemotherapy, but it is stated that more researches are needed to clarify the effect of this type of intervention, so that this type of intervention can be represented as a part of routine treatment of patients [25].

In the study of a session over phone was not effective in reduction of nausea and vomiting symptoms of patients with breast cancer after the last Radiation Therapy that this incompatibility can be associated with low time of follow-up in two weeks and few numbers of phone contacts (one contact) [26]. However, in study on reviewing the effect of phone support on severity of nausea and vomiting of the first half of pregnancy in women in their first pregnancy, mean score of nausea and vomiting in intervention group before and after intervention had a significant difference ($p < 0.001$), and it is stated that phone support decreases severity of nausea and vomiting of pregnancy, therefore, it is recommended as an effective and available method [27].

Presence of contradiction in results of conducted researches can be one of the reasons that conducting more researches in this area is needed. Although in the present study, in order to control disturbing variables and possible protection, sampling of subjects was randomly done in two groups of experiment and control, there were some limitations in doing this study. Awareness of patients about cancer and side effects resulted from chemotherapy might have been changed through conversation with other patients or other media etc. In addition, by considering this point that in mobile software-based education method of the present study, only one written and education videos have been used to represent educational content, maybe, if other techniques such as a film-animation had been used, the results of study would have shown other changes in reduction of chemotherapy side effects. Moreover, due to time limitation, researchers were not able to evaluate long-term effects of the techniques. Therefore, it is recommended to compare effects of this education method in

future researches using different techniques, and consider wider time-limit to evaluate effects of the educations.

Conclusion

As it was stated, the present study showed that the severity of nausea and vomiting in the mobile software-training program has decreased compared to before training. Therefore, researchers believe that by providing the necessary training to these patients, it can be expected that the severity of nausea and vomiting of patients will be reduced to some extent and better conditions and results will be obtained in the subsequent treatment stages of these patients. Therefore, nurses can use this low-cost and effective training to control and reduce these disorders.

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