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The effect of self-care education with smart phone applications on the severity of mucositis and infection after stem cell transplantation in leukemia patients

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Abstract

Introduction: Side effects after stem cell transplantation are still widespread despite huge advances, and self-care education is of paramount importance in such patients. This study aimed to determine the effect of self-care education using smart phone applications on the post-SCT severity of mucositis and infection in leukemia patients.

Materials and methods: This clinical trial study was conducted on 104 SCT patients with leukemia who were assigned to two intervention and control groups with the blocked randomization method. In the control group, patients received routine care, and self-care education with smart phone applications, in addition to routine care, was provided to the intervention group. The questionnaires for transplantation side effects were completed by the control and intervention groups 2 weeks, 1 month, and 3 months after the start of the intervention. Data were analyzed with Chi-square, Fisher's exact, Mann-Whitney, and Friedman tests using SPSS version 25 software.

Results: The severity of mucositis in patients was significantly different in the two groups at all three post-transplantation time points (2 weeks, 1 month, and 3 months) (p-value = 0.000). Patients' infection levels in the two groups differed significantly at all three post-transplantation time points (2 weeks, 1 month, and 3 months) (p-value = 0.000).

Conclusion: The post-SCT severity of mucositis and infection is influenced by self-care education using smart phone applications.

Clinical trial code: IRCT20100725004443N28

Introduction

Acute leukemia accounts for about 8% of total human cancers and is the fifth most common cancer worldwide (1, 3). Due to the trend of demographic changes and increase in life expectancy in Iran, cancer incidence is predicted to reach from 84,800 in 2012 to 129,700 in 2025, with a 35% increase in the incidence of cancerous people (4). Acute leukemia is commonly treated with chemotherapy and stem cell transplantation (SCT) (7). Unlike other methods, chemotherapy is a systemic technique that results in the incidence of multiple side effects, such as nausea, vomiting, anxiety, depression, and fatigue (8, 9). As one of the treatment methods for acute leukemia, SCT has grown rapidly during the last two decades and reaches about 100,000 cases per year (10, 11).

SCT-related physical side effects include early direct toxicity caused by chemotherapy and radiation therapy, acute graft-versus-host disease (GVHD), infection, pain, frequent re-hospitalization, and many hospitalization days to treat complications. Common mental complications include anger, fear of disease recurrence, post-traumatic stress reactions, cognitive impairment, occupational disability, decreased life satisfaction, reduced adaptability and self-confidence, and elevated emotional tensions (12, 13).

Among the mentioned complications, mucositis is one of the most common complications after chemotherapy and SCT in leukemia patients, causing oral ulcers, severe pain, and the risk of infection in oral ulcers. On the other hand, after improving blood cell count and discharge from hospitals, leukemia patients undergoing SCT may require frequent and long-term hospitalization because of GVHD complications (16%), infection (28%), gastrointestinal complications (18%), and fever without known infection (26%), and therefore prevention of these complications is of paramount importance (8, 14). Polito et al. reported the development of mucositis in about 40% of chemotherapy patients (15).

During hospitalization, the care period, and discharge from hospitals, questions usually arise for these patients about the self-care procedure, such as a proper diet, the allowed activity level, the disease complications, and their monitoring and management procedures. However, the education provided to these patients is limited to the usual education, and they do not receive continuous education in this context (16, 17). Since most patients and their caregivers are responsible for monitoring and managing the side effects of their treatment at home, self-care education is one of their essential requirements (18). Because nurses are actively present in all stages of SCT and patient care, they can play an essential role in self-care education for these patients (19). Face-to-face education in these patients increases the risk of infection transmission, and educational methods should be used that includes minimal communication with patients (20).

A modern educational tool is mobile technology, which provides learners with constant access to learning at home, at work, and on the go, and has eliminated many limitations and inefficiencies (21, 22). Furthermore, the impact of mobile phone applications on the improvement and reduction of cancer-induced complications compared to traditional methods has been established in a plethora of studies (9, 23, 24).

Therefore, there is a need for minimum face-to-face communication with these patients, providing continuous and persistent education, and increasing their self-care ability given the limitations of traditional education methods. Therefore, this study aimed to determine the effect of self-care education with smart phone applications on post-SCT mucositis severity and infection rate in leukemia patients.

Materials and Methods

Sitting

This randomized clinical trial study was carried out on a population of leukemia patients undergoing SCT hospitalized at the transplantation wards of Shariati Hospital (affiliated with Tehran University of Medical Sciences) in Tehran during 2019–2020. The study sample was a group of patients hospitalized at the bone marrow transplantation ward who were eligible for inclusion criteria, namely minimum literacy, age of 15–60 years, possessing an Android mobile phone by patients or their caregivers (families), no diagnosed psychological disorders, and no simultaneous client's participation as a subject in another investigation. Exclusion criteria were transferring the patient to other treatment centers during the study, withdrawal of the patient's family from participation, exposure of the patient to the severe disease stage or death throughout the study, and the patient's reluctance to use smart phone applications.

The sample size was calculated based on a significance level of 0.05, a test power of 80%, and assuming at least a 25% statistically significant reduction for each of the qualitative variables related to the effect of self-care education with smart phone applications on post-SCT side effects in leukemia patients. A sample size of 104 subjects in two groups (n = 52 per group) was estimated using the following formula. It should be noted that an incidence rate of 0.5 was assumed for each qualitative variable.

$$n = \frac{\left(z_{1-\raisebox{1ex}{α}/\raisebox{-1ex}{2}}\sqrt{2\,\bar{p}\,\bar{q}} + z_{1-\beta}\sqrt{p_1 q_1 + p_2 q_2}\right)^2}{\left(p_1 - p_2\right)^2}$$

$$\bar{p} = \frac{p_1 + p_2}{2}$$

Sampling

Qualified patients were included in the study purposively based on a list of names in the ward and were randomly allocated to two intervention and control groups. Sampling was performed in two steps because of the need for long-term hospitalization of patients for the treatment process completion and the unavailability of a high sample for sampling in one step. To this end, half of the intervention group and half of the control group from the other transplantation ward at the Shariati Hospital were investigated at the same time as this group. The wards of the test and control groups were selected by a draw, and the two wards were not connected to each other. Other required subjects were sampled 1 week after the end of the study time for these two groups, lasting from October 23, 2019, to October 23, 2020.

Intervention

The approval and a clinical trial code were obtained from the ethics committee. A letter of introduction was then presented to the management of Dr. Shariati Hospital in Tehran and the head of the transplant ward. Thereafter, demographic and disease information were collected through the patients and their medical records at the visiting time of the transplant clinic to prepare for chemotherapy hospitalization before transplantation. After the hospitalization of patients and the start of sampling, routine care and education, including a group education session before transplantation by a lecture, were carried out for the control group patients in the transplant center. In addition to routine education and care, smart phone applications (developed by the research team) were installed on the mobile phones of patients in the intervention group or their caregivers (for those who needed a caregiver). The use and working with the smart phone application were taught and trained with the patients or their caregivers, and their questions were answered by the researcher. This smart phone application includes the introduction of various leukemia types, treatment methods, familiarization with bone marrow transplantation and its procedures, possible side effects and self-care methods of these patients, necessary education for proper post-transplantation nutrition, education on control infection, cleaning, bathing, hand washing, oral and dental hygiene, the procedure and extent of visiting and communicating with companions, observing the related principles, possible disease side effects, prevention methods, and early detection, relief of symptoms, mouth ulcers, and mucositis. The educational content was approved by four faculty members of the faculty and transplant ward. It should be noted that all patients initially received a pre-transplantation dose of chemotherapy as a transplant preparation regimen. Stem cell injection and bone marrow transplantation were performed a few days after chemotherapy, and the whole process lasted about 1 month. After this period, the patient was discharged from the ward and isolated at home for at least 3 months. According to the patient's treatment process, the severity of mucositis and infection was respectively evaluated with a visual analog scale (VAS) and a Khavar oncology scale (KOS), both of which were completed for both control and intervention groups 2 weeks, 1 month, and 3 months after the start of the intervention. The mobile phone number of the researcher was provided to the intervention group to make contacts in the case of any possible problem or question concerning working with the smart application. The patients' phone numbers were also obtained and kept in a study list by the researcher. To ensure that the test group used the smart application, the researcher visited the patients and answered their possible questions once a week in the morning or evening for at least 10 min depending on the patient's desire.

Data collection tools

In this study, data collection tools were two questionnaires on demographic and disease characteristics and the VAS and KOS to assess the severity of mucositis and infection based on the oral health index of the World Health Organization (WHO), the oral mucositis score (OMS) table, and the assessment of infection incidence based on

symptoms and test results. To measure the re-hospitalization rate, information was answered on the number of hospitalization days, frequency of hospitalization, and the reason for hospitalization. The rate of non-routine visits was examined using questions about the reason for the visit and the frequency of visits.

The questionnaire on demographic and disease characteristics consisted of information about age, gender, marital status, education level, employment status, the place of residence, type of insurance, and disease information including the type of leukemia, date, and type of transplant in the subjects. This form was completed through interviews with patients and their families. The clinical and laboratory signs and symptoms of infection in SCT patients were recorded using a researcher-made form for the clinical and laboratory signs and symptoms of infection, such as fever and chills, burning sensation or pain during urination, the presence of abnormal airway secretions, and the CMV-PCR condition, which were recorded by the researcher. For diagnosis and severity of mucositis, a standard form was prepared based on the WHO criteria for the evaluation of oral mucositis based on the criteria used in other studies. Accordingly, the severity of mucositis was classified into grade 0 (no mucositis), grade 1 (oral mucosa erythema without sores and pain), grade 2 (oral erythema with sores but the patient's inability to eat and swallow food), grade 3 (oral sores and painful swallowing in the patient but the ability to drink liquids), and grade 4 (the patient's ability to swallow food but not drink liquids).

To determine the validity of the questionnaires of demographic and disease characteristics using the face and content validity method, the tools were prepared and provided to ten faculty members as the experts in this field at the School of Nursing and Midwifery in Tehran. Their reviewed and modified tools were used with the final approval of the supervisor and advisor.

Analysis of data

Data were analyzed by descriptive statistics with frequency, frequency percentage, mean, standard deviation, minimum, and maximum. The data were analyzed inferentially with the Chi-square test, Fisher's exact, the Mann-Whitney test, and the Friedman test using SPSS version 25 software.

Results

In both groups, the age of most participants was < 30 years, most of whom were men and mostly married. In both groups, most of the participants held academic degrees and were of the AML leukemia type. According to the Chi-square test results, the two groups were not statistically different in terms of age, gender, place of residence, marital status, education level, and the frequency of leukemia type and were similar in these parameters ($p > 0.05$).

The results of the t-test revealed that the two groups were significantly different in terms of the frequency of re-hospitalization (p-value = 0.000) and the frequency of unscheduled visits to the clinic (p-value = 0.000). The results of Fisher's exact test indicated that the post-transplantation frequencies of urine culture (p-value = 0.286) and PCR (p-value = 0.194) were not statistically different between the two groups. According to the results of Friedman's test (Table 1), the mucositis severity variable was statistically different in leukemia patients undergoing SCT in both groups at all three time points, i.e., 2 weeks, 1 month, and 3 months after transplantation (p-value = 0.000).

Table 1
The frequency distribution of mucositis severity in leukemia patients undergoing SCT in control and intervention groups at all three time points, i.e., 2 weeks, 1 month, and 3 months.

Group	Variable											
	Intervention		Control		Intervention		Control		Intervention		Control	
	2week				1 Mont				3 Mont			
	F	%	F	%	F	%	F	%	F	%	F	%
Grade 0	9	17.3	0	0	22	42.3	0	0	52	100	28	53.8
Grade1	9	17.3	0	0	30	57.7	21	40.4	0	0	18	34.6
Grade2	21	40.4	26	50	0	0	25	48.1	0	0	3	5.8
Grade3	13	25	19	36.5	0	0	6	11.5	0	0	3	5.8
Grade4	0	0	7	13.5	0	0	0	0	0	0	0	0
total	52	100	52	100	52	100	52	100	52	100	52	100
Test results	p−value=.000				p−value=.000				p−value=.000			

The results of the t-test (Table 2) showed a statistically significant difference in the frequency of fever times in the two groups (p-value = 0.000).

Table 2
The frequency distribution of the frequency of fever times in leukemia patients undergoing SCT in control and intervention groups and the results of the comparison test

Group	Intervention		Control	
Patient's fever times	F	%	F	%
0	12	23.07	0	0
1	25	48.07	0	0
2	8	15.38	11	21.2
3	0	0	17	32.7
4	0	0	15	28.8
5	0	0	3	5.8
6	7	13.48	6	11.5
Total	52	100	52	100
Mean ± SD	SD = 3.53	X = 1.38	SD = 1.22	X = 1.64
Test results	t = −7.560 df = 102 p−value = 0.000			

Based on the results of the t-test (Table 3), a statistically significant difference was observed for the frequency of chilling times in the two groups (p-value = 0.000).

Table 3
The frequency distribution of chilling times in leukemia patients undergoing SCT in control and intervention groups and the results of the comparison test

Group	Intervention		Control	
Patient's chilling times	F	%	F	%
0	41	78.84	10	19.2
1	4	7.7	26	50
2	7	13.46	16	30.8
Total	52	100	52	100
Mean ± SD	SD = 0.6298	X = 0.2692	SD = 0.70444	X = 1.1154
Test results	t = −7.560 df = 102 p−value = 0.000			

As indicated by the results of the Chi-square test (Table 4), the frequency of abnormal airway secretions was significantly different in the two groups (p-value = 0.003). Also, the results of Fisher's exact test (Table 4) showed that the frequency of dysuria was significantly different in the two groups (p-value = 0.000).

Table 4
The frequency distribution of abnormal airway secretions and dysuria in leukemia patients undergoing SCT in control and intervention groups and the results of the comparison test

Group		Variable			
		Airway secretions		dysuria	
		Yes	NO	Yes	NO
Intervention	Frequency	9	17.3	0	52
	percent	43	82.7	0	100
	Total	52	100	52	100
Control	Frequency	23	44.2	13	32
	percent	29	55.8	25	75
	Total	52	100	52	100
Test results		p-value = 0.003		p-value = 0.000	

Table 5
The frequency distribution of post-transplantation CMV and Blood culture in leukemia patients undergoing SCT in control and intervention groups and the results of the comparison test

Group		Variable											
		CMV				Blood culture				Sputum culture			
		Pos	Neg	NO	Total	Pos	Neg	NO	Total	Pos	Neg	NO	Total
Intervention	F	9	26	17	52	0	44	8	52	4	14	34	52
	%	17.3	50	32.7	100	0	84.6	15.4	100	7.7	26.9	65.4	100
Control	F	23	22	7	52	0	35	17	52	12	23	17	52
	%	44.2	42.3	13.5	100	0	67.3	32.7	100	23.1	44.2	32.7	100
Test results		p−value = 0.005				p−value=.039				p−value = 0.003			

The results of the Chi-square test (Table 5) indicated a significant difference between the two groups in the frequency of post-transplantation CMV (p-value = 0.005), blood culture (p-value = 0.039) and sputum groups (p-value = 0.003).

Discussion

The present study aimed to determine the effect of self-care education with smart phone applications on the post-SCT severity of mucositis and infection in leukemia patients. The results demonstrated statistically significant differences in the severity of mucositis in leukemia patients undergoing SCT in the two groups at all three time points (2 weeks, 1 month, and 3 months after transplantation). Therefore, it can be claimed that self-care education with smart phone applications reduces mucositis severity in leukemia patients undergoing SCT. This result is in line with that of Rodgers et al. (2013) who reported a decrease in the severity of mucositis and oral ulcers in the intervention group in the first 100 days after the intervention (25). Similar to our findings, Dehabadi et al. (26) presented evidence that most of participating patients suffered from ALL, and most of the patients showed oral mucositis in the first trimester of treatment, but these results were not observed in the second trimester. In line with this finding, Rafik Fathallah et al. found positive and significant correlations between physical needs, social needs, routine life activities, and patients' level of awareness after SCT, and physical and psychological needs were lower in patients with a higher level of awareness than the other patients. Thus appropriate awareness and knowledge can reduce the post-SCT needs of patients (27). Concordant with this finding, Vale et al. observed that 60.7% of patients developed mucositis after SCT, and a preventive regimen could effectively reduce the process of mucositis in these patients (28). Guberti et al. also claimed that 78% of SCT patients experienced mucositis, and using the applied protocol reduced the severity of their mucositis and improved their quality of life, which is in agreement with our findings (29). In a similar study but with a different intervention, Hadid et al. found very high mucositis levels in chemotherapy patients in grades 3 and 4, and palifermin could reduce mucositis severity in patients undergoing chemotherapy (30).

Based on the results of the present study, it can be concluded that self-care education with smart phone applications reduces the severity of mucositis in leukemia patients undergoing SCT. Since a common problem of these patients after transplantation is mucositis, which makes eating and drinking difficult for these patients, this type of self-care education is suggested for these patients to reduce post-transplantation side effects and problems.

The results of the t-test showed that the two studied groups were statistically different in the frequency of fever and chills. The Chi-square test results indicated that the variables of abnormal airway secretions, CMV, and post-transplantation sputum culture were significantly different in patients with leukemia undergoing SCT in the two groups. The results of Fisher's exact test revealed a statistically significant difference in the post-transplantation dysuria variable in leukemia patients undergoing SCT between the two groups, but they were not significantly different in PCR and urine culture variables.

This finding corresponds to that of Keyhanian et al. (31), who found positive culture results in 54% of patients. The most common sites of infection were the urinary system (14.3%) followed by the lung (7.9%). These findings of the present study are consistent with those of Khanbabayi et al. (32), who reported positive laboratory tests in favor of infection in 10% of patients who received an implanted port, in addition to clinical symptoms of infection. Likewise, Rozveh et al. found that SCT patients required continuous follow-ups in terms of post-transplantation self-care and its complications, and they would receive the necessary education to promote self-care and prevent post-transplantation complications (33). Similarly, Arbabi Sarjou et al. observed that self-care intervention was the only variable that played an important role in mucositis prevention, and patients should be provided with the necessary advice and education in this context because post-transplantation complications could affect the patient for up to 8 weeks (34). Kazempour et al. also found that self-care education based on the theory of planned behavior could effectively promote self-efficacy, and self-care education would improve their quality of life and prevent many post-transplantation complications, such as post-transplantation infections, to a high extent by increasing patients' self-confidence (35). To confirm the findings of the present study, Styczyński et al. highlight the necessary continuing education for at least 3 months after transplantation. They conclude that late post-transplantation care can be improved by the focus on at-risk groups and better identification of infections of "unknown origin" (36).

The analysis of research results showed that the infection rate was much higher in the control group than in the intervention group. Self-care education with smart phone applications reduced the infection rate in leukemia patients undergoing SCT. Thus, self-care education with smart applications is recommended to reduce the incidence of infection, which is a major post-transplantation problem in these patients.

The results of the t-test indicated that the variables of re-hospitalization and unscheduled visits to the clinic were statistically different in the two groups. The average frequency of re-hospitalization was far lower in the intervention group than in the control group. It can, therefore, be concluded that self-care education with the smart application reduces the re-hospitalization rate and unscheduled visits to the clinic in leukemia patients undergoing SCT. This finding of the present study corresponds to that of Zulfaqari et al., who claimed that telephone follow-up care could reduce re-hospitalization in patients after heart surgery. Therefore, they recommended the use of telephone follow-up care in these patients. This finding of the present study agrees with those of Arbabi Sarjou et al. (34) and Rozveh et al. (33), who pointed out self-care as a factor that should be considered in all patients after SCT to significantly reduce transplantation complications and re-hospitalization of patients. In line with this finding, Kazempour et al. found that self-care education based on the theory of planned behavior could effectively improve self-efficacy and its dimensions in patients after SCT. By improving these dimensions and increasing patients' self-confidence, self-care education improves their quality of life and prevents post-transplantation complications (e.g., re-visits) to a great extent (35).

Conclusion

The results of the present study demonstrate that post-SCT side effects are influenced by self-care education with smart phone applications. Therefore, it is recommended to use this application to reduce the severity of mucositis and infection in leukemia patients who are candidates for transplantation to reduce the mucositis and infection rate of SCT.

Declarations

Ethical Approval: This study observed the publication rules contained in the Declaration of Helsinki (code of ethics IR.TUMS.FMN.REC.1398.039), and this article was prepared by taking all ethical standards needed for publication into consideration. all the prerequisites are present for human ethics as the statements for (Humans Ethics Statement, Adult Consent To Participate Written).

Competing interests

The authors declare no conflict of interest.

Authors' contributions

RJ: Author of the article, RA: Sample collection, MZM: supervisor and supervisor

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Availability of data and materials

The data are available and will be made available to the journal if needed in accordance with ethical standards in research.

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Figures

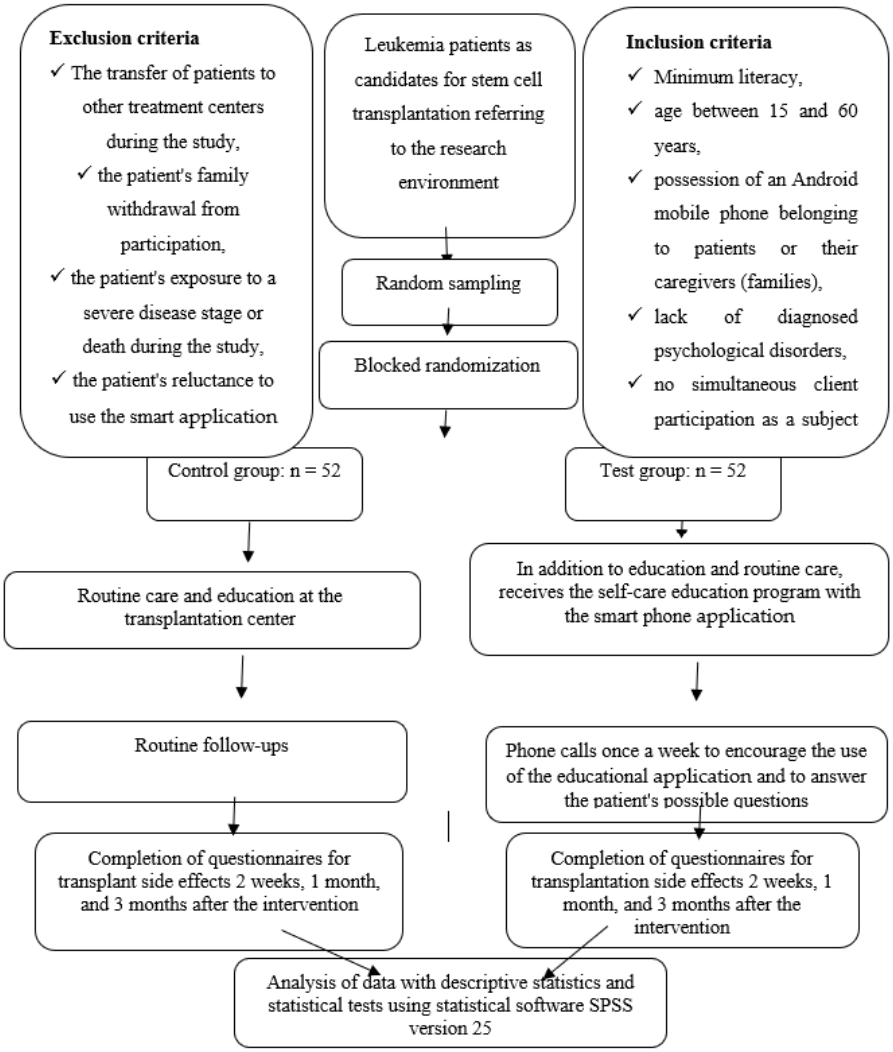


Figure 1

Legend not included with this version