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Effectiveness of a Telenursing System on Side Effects of Chemotherapy by a Crossover Trial

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Abstract

Background: This crossover trial aimed to examine the efficacy of the Telenursing Symptom Management System for Chemotherapy in Outpatient Treatment (T-SCOT) in reducing the side effects in patients undergoing outpatient chemotherapy. Methods: Using a tablet computer, participants were asked to provide information on various items, including fever, nausea, hair loss, fatigue, and vital signs. Both the participants and researchers automatically monitored time-dependent changes in symptoms, and the researchers proposed concrete measures to reduce patients' complications. The primary endpoint was the M. D. Anderson Symptom Inventory (MDASI-J) score. The secondary endpoint, Quality of Life (QOL) was evaluated using the Quality of Life Questionnaire for Cancer Patients Treated with Anticancer Drugs (QOL-ACD). Results: This study included 20 patients who met all the inclusion criteria, 14 of whom agreed to participate in the study. There was no significant difference between the MDASI-J and QOL-ACD pre- and post-comparison of the primary and secondary evaluations in the intervention group. The control group had significantly higher scores 3 months after the intervention for symptom intensity ($p = 0.04$) and symptom-induced disruption to life ($p = 0.03$), and the symptoms worsened. The QOL-ACD had significantly lower scores for activity ($p = 0.03$), overall QOL ($p = 0.04$), and total QOL score ($p = 0.02$), resulting in a lower quality of life. Conclusions: Participants used the Internet to obtain information on treatments and side effects and changed their behavior in daily life. It is speculated that the Information and Communications Technology (ICT) literacy in older adults has improved, and they are benefiting from digital utilization.

Keywords

Telenursing, Outpatient Chemotherapy, Symptoms, Complications, Prevention

1. Introduction

The treatment environment for cancer patients undergoing chemotherapy has changed significantly. Cancer patients used to have to stay in the hospital to receive chemotherapy on an ongoing basis. Chemotherapy for most solid tumors is performed on an outpatient basis, except for some hematological cancers. The background to this is the development of cancer drug therapy, social demands for cancer care, and medical economics [1].

Cancer patients live in familiar surroundings and receive treatment while being connected to work, school and society. Nurses need support to maintain and improve quality of life while continuing to treat patients as planned and managing side effects. Therefore, patients are required to avail timely nursing care according to their individual conditions, even at home. Due to the global spread of COVID-19, patients undergoing chemotherapy are at high risk of infection due to immunocompromise. Therefore, it is now possible to receive a medical examination through online medical treatment without visiting a hospital. Similar to online consultations by doctors, telenursing by nurses has a history of being practiced even before the spread of COVID-19.

Adverse events occurring at home must be carefully monitored during outpatient chemotherapy. Several telephone intervention studies have been conducted in patients undergoing outpatient chemotherapy. Telephone interventions have been shown to reduce symptoms associated with cancer and its treatment [2] and improve QOL and satisfaction in patients with [3] [4] [5]. Studies have documented feasibility and high patient adherence and satisfaction with telephone interventions, but recent reviews have concluded that there is little evidence of its impact on health outcomes [6] [7] [8] [9]. The problem with telephone intervention includes cases in which nurses cannot speak to patients in a timely manner when they call, or in cases where nurses cannot see facial expressions and make decisions based solely on the patient's chief complaint. Since the patient's condition changes daily, it is necessary to provide timely assessment, information provision, and consultation support.

On the other hand, studies on telenursing using applications for patients with diseases other than cancer are being conducted [10] [11] [12]. Interventional studies of patients using clean intermittent urinary catheterization showed its potential to complement conventional care. Telenursing is a promising strategy to make nursing care feasible in different health situations, mainly to help patients with chronic illnesses [13]. Similarly, telenursing for patients with heart failure has been shown to be effective in improving the QOL of patients, preventing readmission, and improving cost-effectiveness [14] [15].

It is difficult for nurses and doctors working in hospitals to check the biometric information of cancer patients receiving home care. As per the researcher's experience usually the nurses and doctors are too busy in their duties and the time might not be enough for the patients visiting the hospital. In addition, in the case of elderly people in rural areas, it is difficult to perform a medical

examination easily because the means of transportation to the hospital are limited. Therefore, medical professionals can understand the patient's condition and solve problems in real time by practicing telemedicine using the Internet.

Cancer patients are mostly elderly. It is difficult for elderly cancer patients to operate ICT equipment and input their own biometric information using the Internet. Therefore, in order to promote remote nursing, it is necessary to improve the information literacy ability of elderly cancer patients and to improve the ease of operation of ICT equipment. The use of ICT can visualize the patient's biological information while the patient is in a remote area without visiting the hospital, thereby reducing unnecessary hospital visits and emergency hospitalization, and contribute to medical cost reduction.

Nurses collect the physical symptoms of cancer patients by interviewing and the Internet. We have developed a system that can store biometric information, such as blood pressure and pulse, measured by cancer patients in the cloud using Bluetooth, which is a wireless communication technology, and collect the information from remote locations. The system name is "Telenursing Symptom Management System for Chemotherapy in Outpatient Treatment" (T-SCOT). We aimed to conduct a crossover trial using the T-SCOT. The purpose of the present crossover study was to examine the efficacy of T-SCOT interventions in reducing side effects in patients undergoing outpatient chemotherapy in a crossover trial.

2. Materials and Methods

The study period was from March 2020 to August 2021. The target facility was one of the cancer base hospitals in Japan.

2.1. Study Design

This intervention study was based on a crossover control trial. An independent data center provided computer-generated random-allocation sequences. The allocation sequences were maintained centrally, and the results of the assignment were sent automatically to the study participants via email. Participants were randomized to the T-SCOT intervention plus care as usual (CAU) or waitlist control with CAU alone. CAU refers to general treatment and/or care commonly provided by each patient's hospital (e.g., nurse's support). The T-SCOT intervention plus care as usual was the intervention group, and care as usual was the control group. After the washout period, participants in the intervention group were included in the control group, and participants in the control group were included in the intervention group.

2.2. Intervention Programs: T-SCOT

T-SCOT is a system that visualizes the side effects of chemotherapy and provides information on coping behaviors for problem-solving (**Figure 1** and **Figure 2**). The T-SCOT includes the following five steps: 1) answer questions related to the

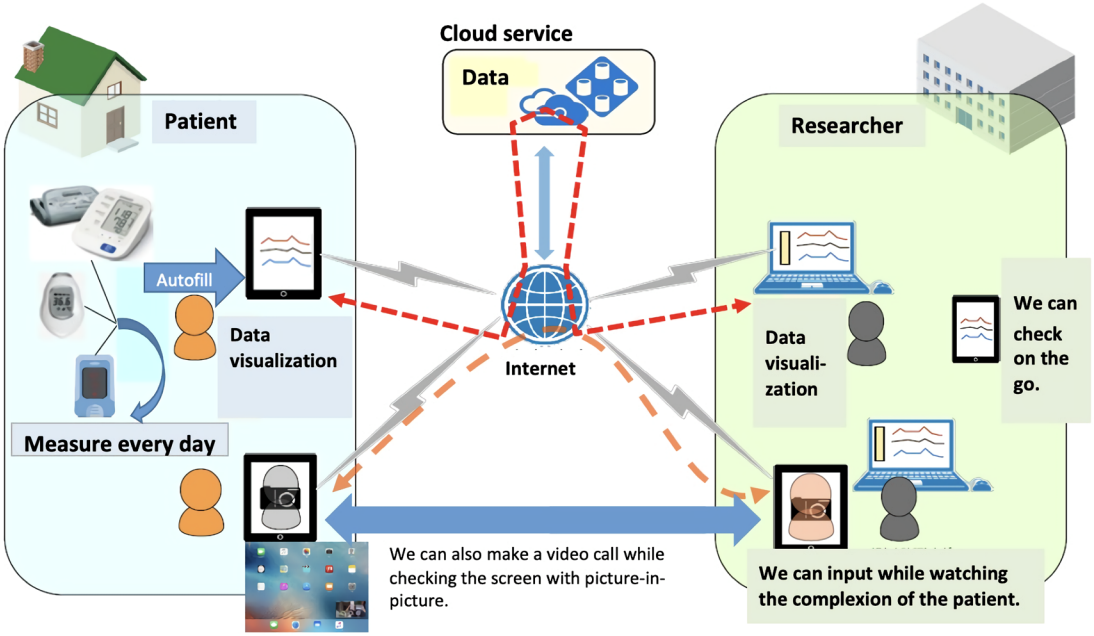

Figure 1. Over of T-SCOT.

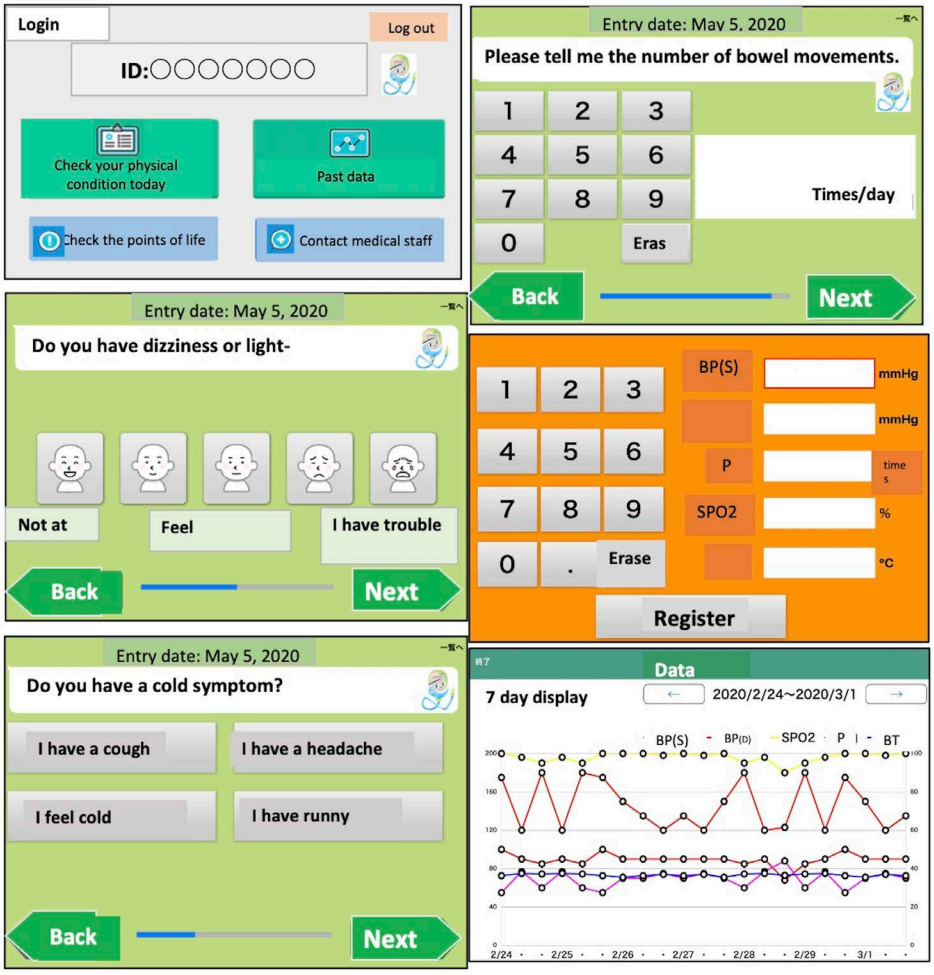

Figure 2. Input screen of T-SCOT.

side effects of chemotherapy [10 items]. a) Do you have appetite? b) Do you have dietary symptoms? (Aphthous ulcer, change in taste, nausea, difficulty swallowing, heartburn: Select all applicable symptoms). c) Do you have a cold symptom? (Coughing, headache, chills, runny nose: Select all applicable symptoms). d) Are you tired? e) Is dizziness or staggering? f) Is there any pain or redness in the palms or soles of the feet? g) Do you have numbness in your fingertip? h) Is there any change in your hair? i) Please tell me the number of defecations. k) How is your overall physical condition today? Symptoms, such as constipation, diarrhea, and skin pigmentation, depend on the drug administered. In this case, add question items in addition to the 10 items mentioned above. 2) Blood pressure, pulse, body temperature, and SPO_2 were measured. The measured data were automatically saved in the cloud using Bluetooth [16].

3) The patient watched a video of coping behaviors for side effects. The video was stored in the T-SCOT and could be viewed at any time by the patient. The contents were a) ingenuity in daily life due to chemotherapy (10 minutes), b) how to deal with peripheral neuropathy due to chemotherapy (3 minutes), and c) characteristics of vinca alkaloid anticancer drugs (2 minutes), d) Taxane anti-cancer drug characteristics (2 min), e) Platinum anti-cancer drug characteristics (2 min). 4) The data entered by the patients were visualized as a line graph. 5) Use the videophone function with researchers if there are any problems or troubles.

The response time for (1) is approximately 2 min. The question items for side effects were also changed according to the drugs used by the patient. It is a method of inputting information from the loaned tablet terminal and selecting a 5-step face scale and the corresponding symptom item. (2) Request to measure vital signs at least once a day at a fixedtime every day. The data measured by the patient were automatically stored on the cloud server via Bluetooth. The contents of (3) carry information of the video of the corrective action in detail, and gather every symptom to a side effect of chemotherapy, and it is suggested to watch the videos. In (4), the progress of the measured blood pressure, pulse rate, body temperature, and SPO_2 are displayed in a line graph and visualized. Both patients and medical personnel were able to share these data. In (5), using the videophone function of the tablet terminal, both users can communicate while looking at their faces. It is not only a means to solve what both the patient and the medical staff want to confirm, but it is also possible to observe the presence or absence of anemia tendency from the skin condition.

For other functions, if the patient does not enter data (T-SCOT and vital signs) in the system for approximately a week, a message prompting the user to enter the system is automatically sent to the patient. In addition, depending on the patient, a trigger point is set for blood pressure, pulse rate, and body temperature. The trigger point of each measured value is based on the reference values shown in academic societies and guidelines. Blood pressure was 140/90 or higher, pulse was 100 or higher, body temperature was 37.5˚C or higher, and SPO_2 was less than 95%. If the value exceeds the trigger point, the researchers are notified au-

tomatically. The researcher contacted the participants via email or videophones. The intervention period was 3 months.

2.3. Participants

The inclusion criteria for participants were as follows: 1) ages 20 - 75 years. 2) Diagnosis of cancer and treatment at an outpatient chemotherapy center. 3) The type of cancer and administration method of the anticancer drug (oral or intravenous drip) did not matter. 4) We did not consider whether it was the first time or a recurrence of cancer. 5) No mental illness. 6) Patients who consented to the research and obtained permission from the doctor. The reason for not limiting cancer diseases is that the T-SCOT can change the question items and respond to differences in cancer types and side effects.

The exclusion criteria for participants were as follows: 1) having active, serious physical disease that affects household and light work, 2) inability to understand Japanese, 3) currently undergoing follow-up and treatment in a psychiatry department or by other mental health professionals, 4) patients who had previously received telenursing, and 5) judged inappropriate for participation by the researchers (e.g., identity theft, duplicate entry, etc.).

For the recruitment method, the attending physician was asked to distribute the research manual to patients receiving outpatient chemotherapy and explain the details of the research to the patients. The researcher explained the contents of the study to the subjects who gave consent. Those who agreed to participate were asked to submit the consent forms.

2.4. Stopping rules for participants

2.4.1. Discontinuation of T-SCOT Intervention

If a participant met any of the following conditions, the research team could discontinue the T-SCOT: however, the participant would not be considered to have dropped out of the trial at that stage and would receive the following protocol assessments: 1) the participant wished to stop the T-SCOT; 2) doctors, nurses, and researchers judged that the risk of T-SCOT intervention was greater than the benefit for any reason; 3) doctors, nurses, and researchers judged that it was difficult to continue T-SCOT intervention because of clinical deterioration; and 4) doctors, nurses, and researchers judged that it was inappropriate to continue T-SCOT intervention for any reason (e.g., when leakage of participant information or system failure due to hacking).

2.4.2. Stopping Assessment

If a participant withdrew consent for assessment, participants would not be followed up.

2.5. Content of Evaluation

The primary endpoint was the M. D. Anderson Symptom Inventory (MDASI-J) [17] [18]. The MDASI-J was designed to assess the severity of common can-

cer-related and treatment-related symptoms, which may better reflect the symptom experience of the cancer population. Several additional advantages of the MDASI-J over other measures were identified. The MDASI-J's 13 "core" symptoms are experienced by most cancer patients, suggesting that the MDASI-J is comprehensive yet brief enough to avoid being a burden to answer. The MDASI-J assesses not only the intensity of cancer-related symptoms but also the level of symptom interference with daily functioning. The instrument's 0 - 10 numerical scale response option format is readily understood even by less-educated patients, easy to translate into other languages, and readily adaptable for telephone, computer, and other electronic forms of administration. For the secondary endpoint, QOL was evaluated using the Quality of Life Questionnaire for Cancer Patients Treated with Anticancer Drugs (QOL-ACD). The QOL-ACD was created to develop a cancer-specific scale that matches Japanese culture and customs, and its reliability and validity have been verified [19]. The questionnaire consisted of 22 items: six items for daily activities, five items for physical condition, five items for mental and psychological status, five items for social activities, and one item for general QOL (face scale). The choices for each question item were evaluated on a scale of 5:1 point was given when the answer was that the QOL was the lowest, and 5 points were given when the answer was the highest. The total QOL-ACD score ranges from 22 to 110, and the higher the score, the higher is the QOL.

The evaluation schedule included a total of four measurements before the intervention, and four weeks, eight weeks, and 12 weeks after the intervention has begun. For the evaluation of the intervention group, we created a format in which MDASI-J and QOL-ACD can be answered in the T-SCOT system. The participants responded within this format. CAU requested a response by mail.

2.6. Harms

No specific or serious adverse events were observed in participants who used T-SCOT. However, using the T-SCOT might lead to psychological distress in some participants, depending on their psychological state. We would evaluate these potential adverse events by qualitative evaluation of the intervention, as previously mentioned.

2.7. DATA Analysis

Descriptive statistics such as numbers, percentages, means, and standard deviations were used to present the descriptive characteristics of respondents in both the experimental and control groups. Fisher's exact test was used to compare baseline variables between the experimental and control groups. The Shapiro-Wilk test was used to evaluate the normal distribution of the quantitative variables. The paired t-test and Wilcoxon test were used to analyze the pre- and post-test values of each group. All statistical analyses were performed using SPSS ver. 25.

2.8. Sample Size Estimation

The sample size was calculated from the average MDASI-J score of a previous study (Yamamoto *et al.*, 2021; Ito *et al.*, 2015). For a sample size based on 0.8 power to detect a significant difference of 0.05 (two sided), 15 participants were required for each arm. In this study, an effect size of 5 and a variation of 15 were used. Assuming that 10% of the initial entries would drop out, we would need to recruit 25 participants for the trial.

2.9. Study Period

The study period of this trial will be from April 2020 to March 2022 and the participant entry period will be from May 2021 to January 2022.

2.10. Ethics and Dissemination

The study was subject to ethical guidelines for clinical studies published by Japan's Ministry of Education, Science and Technology and Ministry of Health, Labor, and Welfare and the modified Act on the Protection of Personal Information, as well as the ethical principles established for research on humans stipulated in the Declaration of Helsinki and further amendments thereto. If important protocol modifications are needed, investigators will discuss them and report them to the review board for approval. Regarding dissemination, the results obtained will be submitted for publication in peer-reviewed journals. The main and relevant findings are presented at conferences.

3. Results

3.1. Outline of the Participants

We asked 20 candidates to participate in the study and obtained their consent from 14 participants. There were 10 males (71.5%) and 4 females (28.5%) with an average age of 64.8 ± 5.9 years. The types of cancer were gastrointestinal (n = 8, 57.0%), respiratory (n = 4, 28.5%), and mammary gland (n = 2, 14.5%). Four (28.5%) participants are working/employed. The participants had an average of 8.4 months of chemotherapy experience. An outline of the participants is presented in Table 1.

3.2. Comparison before and after MDASI-J and QOL-ACD in the Intervention Group and the Control Group

There was no significant difference between the MDASI-J and QOL-ACD pre- and post-comparison of the primary and secondary evaluations in the intervention group. The control group had significantly higher scores 3 months after the intervention for symptom intensity ($p = 0.04$) and symptom-induced disruption to life ($p = 0.03$), and the symptoms worsened. The QOL-ACD had significantly lower scores for activity ($p = 0.03$), overall QOL ($p = 0.04$), and total QOL score ($p = 0.02$), resulting in a lower quality of life for those in the control group. The comparison results are presented in Table 2.

Table 1. Overview of the study participants (n = 14).

Item		n (%)	mean ± SD
Age			64.8 ± 5.9
sex	man	10 (66.6)	
	woman	4 (33.4)	
Type of cancer	Sigmoid colon	7 (50.0)	
	pancreas	1 (8.3)	
	lung	4 (25.0)	
	breast	2 (16.7)	
Regimen	ZALTRAP + FOLFIRI	3 (16.7)	
	FOLFIRI + Pmab	2 (16.7)	
	GEM/nab-PTX	3 (16.7)	
	FOLFOXIRI + Bmab	1 (8.2)	
	PEM + Pembrolizumab	3 (25.0)	
	EC	2 (16.7)	
Employed/Working		4 (25.0)	
Family structure	Single	3 (25.0)	
	Couple and children	11 (75.0)	
Months of chemotherapy experience			10.3 ± 3.2

Table 2. Comparison of MDASI-J and QOL-ACD before and after intervention (n = 14).

Scale name	Item	Intervention Group			Control Group		
		Before intervention	After intervention	p	Before intervention	After intervention	p
MDASI-J	Severity of symptoms	26.8 ± 13.1	28.8 ± 14.9	0.27	26.9 ± 13.8	24.2 ± 13.5	0.04
	Interference with daily living	10.9 ± 9.2	9.9 ± 8.1	0.08	9.0 ± 8.8	9.8 ± 7.7	0.03
QOL-ACD	Daily activity	28.9 ± 3.1	28.1 ± 2.2	0.39	28.1 ± 4.2	25.9 ± 3.2	0.03
	Physical condition	18.2 ± 5.7	17.5 ± 4.9	0.07	17.3 ± 5.9	16.8 ± 5.1	0.35
	Psychological condition	19.1 ± 3.1	20.5 ± 2.6	0.38	18.2 ± 3.8	18.9 ± 2.9	0.19
	Social attiude	18.2 ± 2.9	18.8 ± 1.9	0.19	17.8 ± 2.9	17.1 ± 1.3	0.13
	Face scale	3.9 ± 0.8	3.9 ± 0.9	0.21	3.9 ± 1.4	3.7 ± 0.3	0.04
	Total score	85.7 ± 13.2	86.3 ± 15.4	0.29	84.8 ± 17.1	81.8 ± 17.2	0.02

MannWhitney U test.

3.3. Comparison of MDASI-J and QOL-ACD between the Intervention Group and the Control Group 3 Months after the Intervention

There was no significant difference in the MDASI-J scores between the intervention and control groups after three months. In the QOL-ACD, the scores of the

intervention group were significantly higher, and the QOL was higher in the mental/psychological state (p = 0.02) and the total QOL score (p = 0.02). The results of these comparisons are presented in Table 3.

4. Discussion

4.1. Participant Characteristics

The 14 participants had an average age of 68 years, and the majority were early stage older adults. The Ministry of Internal Affairs and Communications is working to build various mechanisms to eliminate the digital divide caused by age and disability. According to the 2019 data, the Internet usage rate was 90.5% for those in their 60s and 74.2% for those in their 70s, showing a significant increase in usage compared to the previous year [20] [21]. More than 40% of the older adults who said that they were "healthy" had problems in their daily lives that were solved using the Internet [22]. Participants used the Internet to obtain information on treatments and side effects and changed their behavior in daily life. It is speculated that her ICT literacy in older adults has improved, and they are benefiting from digital utilization. Participants can utilize the T-SCOT by skillfully operating ICT devices and blood pressure measuring devices with Bluetooth. The T-SCOT has specifications that make the characters on the screen larger so that even older adults can easily operate them. The measurements were automatically stored in the cloud via Bluetooth without the participants entering them directly into the tablet. It is presumed that the reason the participants were able to intervene without leaving was that the tablet was designed so that it could be operated easily and did not feel a burden.

Participants were in stages III to IV based on the type of cancer and the content of the regimen, and the progress of their condition. Chemotherapy may have different side effects on anticancer drugs, including their therapeutic effect,

Table 3. Comparison of MDASI- and QOL-ACD after 3 months of intervention (n = 14).

Scale name	Item	After intervention Data		p
		mean ± SD		
		Intervention	Control	
MDASI-J	Severity of symptoms	28.8 ± 14.9	24.2 ± 13.5	0.08
	Interference with daily living	9.9 ± 8.1	9.8 ± 7.7	0.11
QOL-ACD	Daily activity	28.1 ± 2.2	25.9 ± 3.2	0.06
	Physical condition	17.5 ± 4.9	16.8 ± 5.1	0.31
	Psychological condition	20.5 ± 2.6	18.9 ± 2.9	0.02
	Social attiude	18.8 ± 1.9	17.1 ± 1.3	0.12
	Face scale	3.9 ± 0.9	3.7 ± 0.3	0.39
	Total score	86.3 ± 15.4	81.8 ± 17.2	0.02

MannWhitney U test.

from patient to patient. There were three people living alone, and it is probable that the environment was such that the connection with society weakened. Repeated treatments reduce physical strength and increase depression [9] [23] [24]. Previous studies have shown that remote nursing helps reduce anxiety and increase overall satisfaction with medical staff connections [10] [11]. The same is true for the results of this study, and it is presumed that the participants felt reassured that they were connected to medical professionals through the T-SCOT. Prior to participating in the study, the participants were educated by medical professionals about the side effects caused by treatment, the mechanism of occurrence, and countermeasures. Therefore, the participants were informed about coping behaviors for side effects and had successful experiences due to the prior education, and were a group that recognized the importance of self-care.

4.2. Relationship between T-SOCT in the Prevention of Worsening of Symptoms and QOL

The primary evaluation, MDASI-J, showed no significant difference in scores when comparing the sub-items of the intervention and control groups 3 months after the intervention. One reason for this is the presence of various types of cancers and regimens. Second, there was a large difference in the standard of "symptom intensity" of the MDASI-J, and there were variations in the subjective symptoms of the participants. In addition, the support for the patients who have been receiving treatment for about one year at home after drug administration has been sufficiently established. Many participants understood when, and what to do to prevent symptoms after administering an anticancer drug. At the target facility, participants were given a notebook to describe their own daily physical symptoms and education was provided to monitor daily biometric information. In both groups, the environment in which one's vital signs and past changes in physical condition were visualized was considered a factor thatincreased self-efficacy for the prevention of side effects.

The results of the MDASI-J intervention and control groups before and after the intervention showed no changes in the intervention group. In contrast, in the control group, the score was significantly higher and the symptoms worsened after 3 months. The same was true for QOL-ACD, and only the control group had significantly lower scores for three items such as activity and overall QOL after 3 months, and QOL deteriorated. Behind the worsening of the side effect symptoms and QOL of the participants, first, side effects due to the drug are likely to appear due to the continuation of treatment, and second, the patient's daily symptoms are being monitored by the medical staff. Previous studies of patients with gastric and breast cancer who received chemotherapy have shown that active intervention by healthcare professionals leads to a sense of security for the patient [24] [25]. Participants receiving regular care had only one outpatient treatment day with their doctor every 2 - 3 weeks. Patients in the control group could contact the medical institution via telephone if there were any problems. However, it is expected that the patients may be uncertain or hesitant to contact

the medical staff regarding the current symptoms that they are experiencing. The intervention group also accepted T-SCOT interventions well by finding intervals between work and housework and inputting their biometric data into the tablet at a fixed time. It is thought that the patient's sense of security was due to the fact that he or she could check his or her vital signs and the results of visualizing his or her past physical condition from the tablet terminal and the timely reaction from the medical staff. Therefore, the effectiveness of the T-SCOT, which is a new nursing support for cancer patients receiving outpatient chemotherapy, was demonstrated.

5. Conclusions

This crossover trial aimed to examine the efficacy of the T-SCOT in reducing the side effects in patients undergoing outpatient chemotherapy. Participants used the Internet to obtain information on treatments and side effects and changed their behavior in daily life. Medical staff were able to visualize the biological information of cancer patients recuperating at home, and were able to intervene in a timely care. This is a novel and future-oriented study.

It is speculated that the ICT literacy in older adults has improved, and they are benefiting from digital utilization. Therefore, patients who are in constant contact with ICT equipment are less likely to feel a burden while operating it and are likely to be able to use it smoothly. Elderly people are likely to find it burdensome to operate and input ICT. These situations can affect the results of the T-SCOT.

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Conflicts of Interest

The authors declare that they have no competing interests.

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List of Abbreviations in Alphabetic Order

1) CAU: Care as usual

2) ICT: Information and Communication Technology

3) IOT: Internet of Things

4) MDASI: The M. D. Anderson Symptom Inventory

5) QOL: Quality of Life

6) Quality of life questionnaire for Cancer Patients treated with Anticancer drugs

7) TNPM: Tele-Nurse Practice Model

8) T-SCOT: Telenursing Symptom Management System for Chemotherapy in Outpatient Treatment.