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Effectiveness of a Telenursing System to Prevent the Exacerbation of Symptoms in Patients with Cancer Undergoing Outpatient Chemotherapy

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Abstract

During outpatient chemotherapy, adverse events occurring at home must be carefully monitored. We have developed a tele-nursing system that can store physical information such as blood pressure and pulse measured by cancer patients in the cloud by using Bluetooth, which is wireless communication technology, and collect information from remote locations. The tele-nursing system name is T-SCOT. The purpose of this study is to conduct a randomized controlled trial to investigate the efficacy of T-SCOT intervention. Participants are those who receive T-SCOT intervention plus Care as usual as the intervention group, and those who receive only Care as usual as the control group. T-SCOT includes the following five steps: 1) Answer questions related to side effects of chemotherapy [10 items]; 2) Measure blood pressure, pulse, body temperature, and SPO2. The measured data is automatically saved in the cloud via Bluetooth; 3) Watch a video of coping behavior for side effects; 4) The data entered by the patient is visualized as a line graph; 5) Utilize the videophone function with researchers if you have any problems or troubles. Utilization of ICT in telenursing makes it possible to visualize patient's physical information and contributes to the reduction of medical expenses.

Keywords

Telenursing, Outpatient Chemotherapy, Symptoms, Complications, Prevention

1. Introduction

In Japan, due to advances in medical technology and shortening the length of hospital stay, advanced treatment has been provided outpatient. The mainstream of chemotherapy for cancer is outpatient treatment. The background of this is the development of cancer drug therapy, social demands for cancer care, and medical economics reasons [1].

Cancer patients need to be able to continue their outpatient treatment while living their normal and social lives, and to maintain and improve their quality of life. For this reason, patients are required to provide timely nursing care according to their individual conditions even at home. During outpatient chemotherapy, adverse events occurring at home must be carefully monitored. A number of telephone intervention studies have been reported for patients undergoing outpatient chemotherapy. Telephone intervention reduced anxiety and depression [2] and improved/improved QOL and satisfaction in cancer patients [3] [4] [5]. Studies have documented feasibility and high patient adherence and satisfaction, but recent reviews conclude that there is little evidence of impact on health outcomes [6] [7] [8] [9]. The problem with telephone intervention is that it is difficult to collect information in real time on changes in biological reactions of cancer patients due to side effects after chemotherapy. Since the patient's condition changes daily, it is necessary to provide timely assessment, information provision, and consultation support. On the other hand, the study on tele-nursing using applications for patients other than cancer diseases is being practiced [10] [11]. The results of a meta-analysis of diabetic patients were showed that the use of telenursing (vs. usual care) was associated with a significant reduction in HbA1c levels compared to usual care [12]. Similarly, tele-nursing for patients with heart failure was shown to be effective in improving the QOL of patients, preventing readmission, and improving cost effectiveness [13] [14].

However, it is inefficient for the doctors and nurses who are in charge of outpatient treatment to check the vital signs of cancer patients by telephone every day. In addition, in the case of elderly people in rural areas, it is difficult to take a medical examination easily because the transportation means to the hospital are limited. Therefore, medical professionals can solve the problems of telephone intervention by practicing tele-nursing using the Internet.

In order for doctors and nurses to instantly know the biological information of cancer patients who are receiving medical treatment at home, information can be obtained by utilizing ICT technology. By creating an environment for the telenursing system, the nurse can know the patient's physical information in real time while performing the assessment and patient education while in a remote location. The use of ICT can visualize the patient's biological information while the patient is in a remote area without visiting the hospital, reduce unnecessary hospital visits and emergency hospitalization, and contribute to medical cost reduction.

Collect physical symptoms of cancer patients by interviewing and answering

methods using 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 by using Bluetooth, which is wireless communication technology, and collect information from remote locations. The system name is "Telenursing Symptom management system for Chemotherapy in an Outpatient Treatment: T-SCOT". We will conduct a randomized controlled trial using T-SCOT. The purpose of the present randomized study is to examine the efficacy of T-SCOT interventions to reduce side effects in patients undergoing outpatient chemotherapy in a randomized controlled trial.

2. Methods

2.1. Conceptual Framework

The theoretical framework of the study was provided to the Tele-Nurse Practice Model (TNPM) [15]. The TNPM is a theoretical framework nurses can use to define and guide the complex process of care in a telephone encounter. Telenursing provide comprehensive care and information on self-management to patients, and provide resources for health promotion and changes in health behavior in cooperation with other professionals. TNPM shows the advantages and difficulties of grasping the symptoms of patients living at home and assessing their condition by telephone. The basis of TNPM is for medical professionals to properly and accurately grasp the physical information of patients undergoing medical treatment at home. Therefore, in this study, we changed the means of grasping the patient's physical information from telephone to ICT while following this idea. In addition, it is possible to grasp the patient's facial expression by video using a videophone as well as voice when calling with the patient. Videophone support is a qualified nurse with experience in cancer nursing. Telenursing using ICT can easily share patient information with a doctor, and can prepare an environment where patients can receive treatment early.

2.2. Study Design

The present study is an individually randomized, parallel-group trial (**Figure 1**). An independent data center will provide computer-generated random allocation sequences. The allocation sequences are maintained centrally, and the results of the assignment will be sent automatically to the study participants by email. The participants are randomized to T-SCOT intervention plus Care as usual (CAU) or waitlist control with CAU alone. CAU means general treatment and/or care commonly provided by each patient's hospital (e.g., nurse's support, and so on). T-SCOT intervention plus Care as usual is the intervention group, and Care as usual is the control group.

2.3. 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 2**, **Figure 3**).

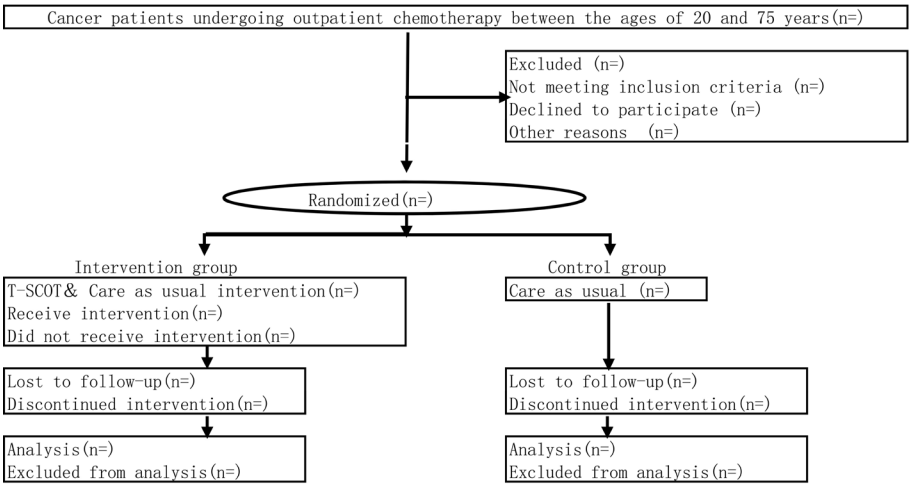

Figure 1. Participant flow diagram.

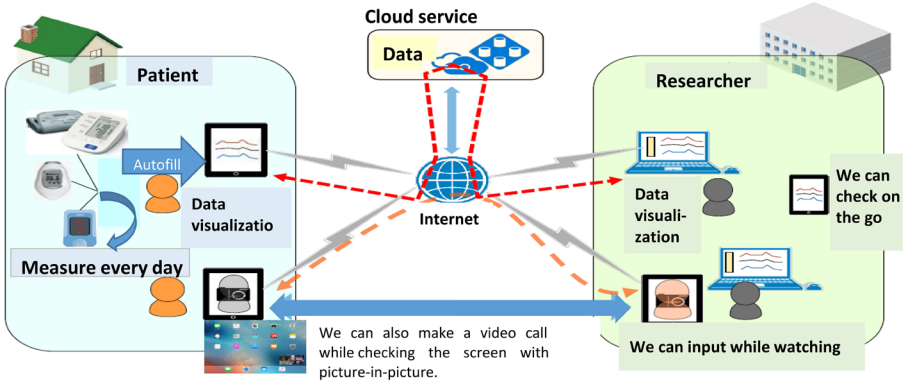

Figure 2. Overview of T-SCOT.

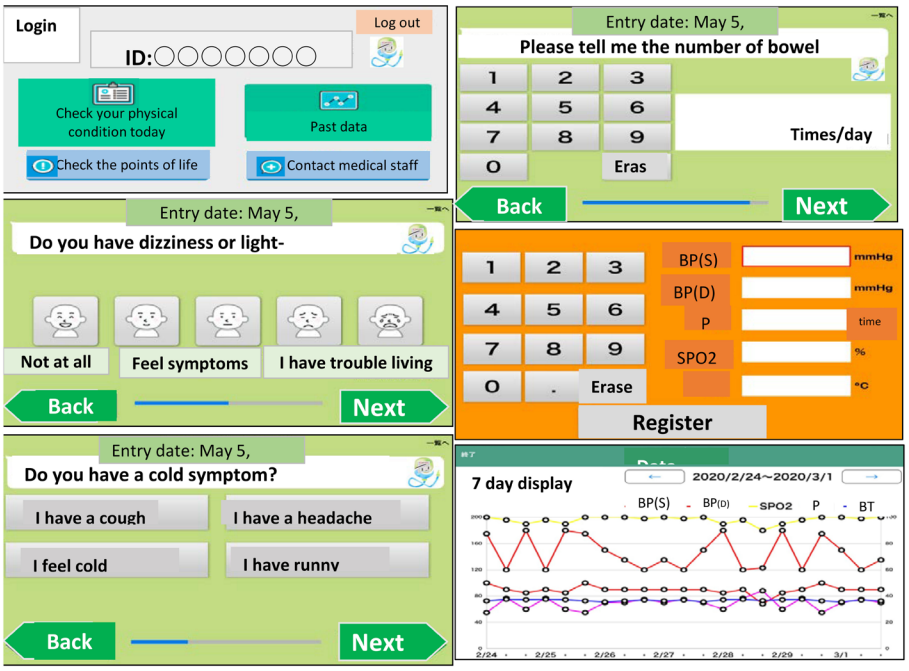

Figure 3. Input screen of T-SCOT.

T-SCOT includes the following five steps: 1) Answer questions related to side effects of chemotherapy [10 items]. a) Do you have an appetite? b) Do you have any 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 there dizziness and stagger? f) Is there any pain or redness on the palms or soles of the feet? g) Do you have numbness in your fingertips? h) Is there any change in your hair? i) Please tell me the number of defecations. j) How is your overall physical condition today? There are symptoms such as constipation, diarrhea, and skin pigmentation depending on the drug to be administered. In that case, add question items in addition to the 10 items mentioned above. 2) Measure blood pressure, pulse, body temperature, and SPO2. The measured data is automatically saved in the cloud via Bluetooth. 3) Watch a video of coping behavior for side effects. The video is stored in the T-SCOT and can be viewed at any time by the patient. The contents are 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 minutes), e) Platinum anti-cancer drug characteristics (2 minutes). 4) The data entered by the patient is visualized as a line graph. 5) Utilize the videophone function with researchers if you have any problems or troubles.

The response time for 1) is about 2 minutes. The question items for side effects are also changed according to the drug used by the patient. It is a method of inputting from the loaned tablet terminal and selecting a 5-step face scale and the corresponding symptom item. 2) Request the measurement of vital signs at least once a day at a fixed time every day. The data measured by the patient is automatically stored in the cloud server via Bluetooth. The contents of 3) carry information of the video of the corrective action in detail gathered every symptom to a side effect of chemotherapy, and watching is suggested. In 4), the progress of the measured blood pressure, pulse rate, body temperature, and SPO2 is displayed in a line graph and visualized. Both patients and medical personnel can share the data. In 5), using the videophone function of the tablet terminal, both can communicate while looking at their faces. Not only a means to solve what both the patient and the medical staff want to confirm, 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 the system for about 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, body temperature, etc. The trigger point of each measured value is based on the reference value shown in academic societies and guidelines. Blood pressure is 140/90 or higher (guideline for the management of hypertension JSH 2019), pulse is 100 or higher (JCS/JHRS 2020 Guideline on Pharmacotherapy of Cardiac Arrhythmias), body temperature is 37.5 or higher (practical guideline of febrile neutrophilia JSMO 2017), SPO2 is less than 95% (The Japa-

nese Respiratory Society). If the value exceeds the trigger point, the researchers will be automatically notified. The researcher will contact the participants by email or videophone. The intervention period is 3 months.

2.4. Participants

The inclusion criteria for participants are as follows: 1) Ages 20 - 75 years; 2) Diagnosed with cancer and receiving treatment at an outpatient chemotherapy center; 3) The type of cancer and the administration method of the anticancer drug (oral or intravenous drip) do not matter; 4) It does not matter whether it is the first time or a recurrence; 5) No mental illness; 6) Those who have consented to the research and obtained the permission of the doctor. The reason for not limiting cancer diseases is that T-SCOT can change the question items and respond to differences in cancer types and side effects.

The exclusion criteria for participants are 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 have previously received tele-nursing; 5) judged inappropriate for participation by the researchers (e.g., identity theft, duplicate entry, and so on).

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

2.5. Stopping Rules for Participants

2.5.1. Discontinuation of T-SCOT Intervention.

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

2.5.2. Stopping Assessment

If a participant withdraws consent for assessment, participants will not be followed up.

2.6. Content of Evaluation

The primary endpoint was The M. D. Anderson Symptom Inventory (MDASI-J)

[16] [17] [18]. MDASI-J was designed to assess the severity of common cancer-related and treatment-related symptoms that may better reflect the symptom experience of the cancer population. Identified several additional advantages of the MDASI-J over other measures. 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 secondary endpoint, QOL was evaluated using Quality of life Questionnaire for Cancer Patients Treated with Anticancer Drugs (QOL-ACD). QOL-ACD was created for the purpose of developing a cancer-specific scale that matches Japanese culture and customs, and its reliability and validity have been verified [13]. The question items consist of 22 items: 6 items for daily activities, 5 items for physical condition, 5 items for mental and psychological status, 5 items for social activities, and 1 item for general QOL (face scale). The choices for each question item are evaluated on a scale of 5; 1 point is given when the answer is that the QOL is the lowest, and 5 points is given when the answer is the highest. The total QOL-ACD score ranges from 22 to 110, and the higher the score, the higher the QOL.

The evaluation schedule will be a total of 4 measurements before, 4 weeks, 8 weeks, and 12 weeks. For the evaluation method of the intervention group, we created a format in which MDASI-J and QOL-ACD can be answered in the T-SCOT system. The participant responds within that format. CAU will request a response by mail.

2.7. Qualitative Evaluation of Intervention

The intervention group operates the tablet terminal for a long period of time to input physical symptoms. Therefore, an interview will be conducted to understand the advantages and disadvantages of the intervention. The interview will be conducted by the researcher and will be conducted online using the videophone of the T-SCOT system. One interview time is about 30 minutes. The interview period shall be within 2 weeks after the end of the intervention period.

The interview items will be as follows: 1) "Please talk freely about the usefulness of the T-SCOT intervention." 2) "Please talk freely about the effectiveness and harms of the intervention, for example, the regular encouraging e-mail." 3) "Did the content of the video and the response of the nurse help?" 4) "Have you ever found it difficult to input T-SCOT?" If the participants permit, the answers will be recorded using a voice recorder.

2.8. Harms

No specific and serious adverse events are presumed in participants who use

T-SCOT. However, using T-SCOT might lead to psychological distress in some participants depending on their psychological state. We will evaluate these potential adverse events by qualitative evaluation of intervention as mentioned before.

2.9. DATA Analysis

Descriptive statistics such as numbers, percentages, mean, and standard deviation were used to present descriptive characteristics of respondents in both the experimental and control groups. Fisher's exact tests were used to compare baseline variables between the experimental and control groups. The Shapiro-Wilk test was used to evaluate the normal distribution of quantitative variables. The Paired t-test and Wilcoxon test were used to analyze the pre and posttest values of each group. All statistical analyses were performed using SPSS Ver. 21.

2.10. Sample Size Estimation

The sample size was calculated from the average MDASI-J score of the previous study [19] [20]. For a sample size based on 0.8 power to detect a significant difference at $p = 0.05$ (two sided), 30 participants would be required for each arm. Assuming that 10% of the initial entries would drop out, we would need to recruit 66 participants into the trial.

2.11. Study Period

The study period of this trial will be from April 2021 to March 2023; the participant entry period will be May 2021 to September 2022.

2.12. Ethics and Dissemination

The study is 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, the investigators will discuss them and report to the review board for approval. With regard to dissemination, the results obtained will be submitted for publication in peer-reviewed journals. The main and relevant findings will be presented at conferences.

3. Discussion

T-SCOT not only the input of physical condition using conventional ICT devices but also various medical devices and information compose the Internet via sensors and wireless communication under the concept of Internet of Things (IOT)., It is a system that can visualize the physical information of the patient. The point of construction of a system that incorporates the concept of IOT into this tele-nursing is original and highly creative. In the specific example, the

measured blood pressure data is automatically accumulated in the cloud using Bluetooth, and the function of collecting the physical information measured by the patient's speech without operating the ICT device is added. That information aids the assessment of nurses and doctors.

In Japan, it is expected that the number of sick people and medical expenses will increase rapidly as the population ages rapidly. Utilization of ICT in tele-nursing makes it possible to visualize the patient's physical information without going to a hospital, reduce unnecessary hospital visits and emergency hospitalization, and contribute to medical cost reduction. At the same time, communication with medical staff can be connected 24 hours a day using ICT, which is expected to improve QOL. There are about 800,000 potential nurses nationwide who leave the medical field due to marriage or childbirth while having the qualifications of a nurse. If the effectiveness of the T-SCOT developed in this study can be proved, the nurse can grasp the physical information of the patient and provide concrete nursing support even at home. In other words, it is possible to utilize potential nurses who cannot leave home due to raising children, which leads to the creation of new employment.

T-SCOT is considering installing machine learning for artificial intelligence in the future. Specifically, it has the function of automatically assessing the physical information of the patient by enhancing the learning processing and judgment processing functions by mini-batch learning by the stochastic gradient descent method. In the future, in addition to the auxiliary role of medical personnel, the tele-nursing system has the potential to actively engage with patients.

4. Limitation of Research

This study is an intervention study utilizing ICT. The target cancer patients are generally elderly, and many are not good at operating ICT equipment. Therefore, patients who are in constant contact with ICT equipment are less likely to feel a burden in operation 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 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) QOL-ACD 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 an Outpatient Treatment