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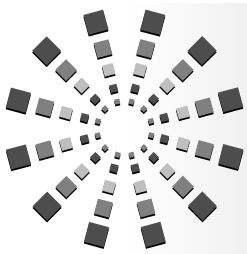

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# Efficacy of an Algorithm-Based Nursing Intervention to Promote a Balance Between Cancer Patients' Social Roles and Outpatient Treatment

## A Quasi-Experimental Study

**KEYWORDS**
Cancer outpatient treatment
Distress
Social role
Work
Algorithm-based nursing intervention

**Background:** Cancer patients undergoing treatment are often unable to balance treatment and work because of the time required for care at the hospital and a desire to avoid problems at work. **Objective:** The aim of this study was to elucidate the efficacy of an algorithm-based nursing intervention (ANI) to promote balance between social roles and outpatient treatment in cancer patients. **Methods:** Participants were outpatients receiving cancer therapy and randomly assigned to a control or an intervention group, the latter to receive ANI for 2 months. The outcomes were assessed using the Distress and Impact Thermometer and changes in employment status. Data from 54 evaluable participants in each group were analyzed. **Results:** Distress and Impact Thermometer scores in the intervention group were significantly lower than those in the control group ($P < .001$). In addition, 2 months later, 20 participants had resigned from their employment or were on leave in the control group (37.0%); this was twice the number in the intervention group, a significant difference ($\chi^2 = 4.573$, $P < .05$). Logistic regression analysis showed that the odds ratio in the control group was 3.6 times that of the

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intervention group of having resigned. **Conclusion:** The ANI appears to have reduced distress and impact scores associated with the course of treatment and to have reduced the likelihood of resignations at 2 months after implementation. **Implications for Practice:** The intervention appears to be effective and may be a new tool for use by outpatient oncology nurses.

## ■ Study Background and Objectives

One in 2 people in Japan has cancer, and approximately 1 million new cases of cancer occur each year. Of those with cancer, 30% are working-age between 15 and 64 years.[1] Healthcare reform has been promoted because of rapid aging of the population and rising medical costs; the duration of hospitalization has been shortened, and recuperation takes place in outpatient departments and communities rather than in hospitals.[2] With respect to cancer treatment, outpatient treatment for chemotherapy and radiation therapy has become mainstream, and the number of adult patients with cancer (hereafter referred to as patients) who fulfill roles in their communities while continuing treatment is increasing rapidly. For these patients, retaining employment and fulfilling social roles increase their quality of life,[3] self-esteem, and sense of worth.[4,5] In addition, they have been reported to feel a connection with society[5] and the restoration of health and normality of life.[6] In a previous study, one survivor stated, "I'm sick of cancer, but I feel I'm alive now because I'm working"[7]; work can be a source of motivation to manage cancer.

However, in a large-scale survey conducted by Yamaguchi et al,[8,9] approximately 30% of patients who were diagnosed with cancer had resigned from work voluntarily. Adult patients undergoing treatment are often unable to balance treatment and work because of the time it takes for medical care and a desire to avoid problems at the workplace. In addition, when there are difficulties with continued treatment, refractory symptoms such as peripheral neuropathy and fatigue might not be alleviated,[9,10] and the cost of treatment can cause financial pressure.[11] Because cancer and its treatment cause psychological, social, and physical distress, patient support requires evidence and a personalized approach to distress relief. The Japanese government enacted the 2006 Cancer Control Basic Law to promote the relief of these types of distress. Since 2012, medical staff have focused on early pain screening and work support. However, an interim evaluation in 2015 documented that physical and mental distress in cancer patients was controlled in only 60%; 40% were not reporting relief of distress. The number of employees leaving work had not improved, and screening was being strengthened as a countermeasure.[12]

Cancer nursing's support of outpatients includes support for their mental health from the time of cancer diagnosis forward and the improvement of mental and physical assessment and symptom management. Such support promotes harmony among social roles, including employment and outpatient treatment. Highly skilled nurses with rapid judgment and execution skills and sufficient resources, including staffing, are required. However, in Japan, the outpatient nurse-to-patient ratio of 1:30, as stipulated in the Medical Care Act of 1948, remains the same, leading to chronic shortages of nurses.[13]

For patients, the ability to maintain their social roles during treatment is important, as it is connected to both survival and self-worth. In addition, social roles include childcare, nursing care, family responsibilities, and roles in the local community as well as work. Although work-related research has been conducted, no supporting research has been conducted to focus on social roles.

Consequently, we have conducted numerous mixed-method studies to develop nursing support that promotes a balance between the social roles of survivors, including employment, and outpatient treatment.[14–18] A qualitative descriptive study that targeted specialized outpatient care showed 5 elements of nursing that promote treatment and the execution of roles.[18] Referring to these studies and articles,[19,20] we developed a "nursing algorithm that promotes balance between social roles and outpatient treatment of cancer survivors."[17,18] The present algorithm was based on (1) building a relationship (connecting with patients and learning their needs), (2) improving the balance between mind and body (improved judgment and self-management skills for adverse events and pain), and (3) the role of nurses in maintaining social roles including employment. We repeated steps that reflected specialist opinions, expert decisions, and their foundations; made improvements after the preliminary tests; and prepared a final version to allow all nurses involved with outpatient care, including nursing generalists, to execute it. Therefore, the purpose of this study was to demonstrate the effectiveness of using algorithm-based nursing interventions (ANIs) to promote a balance between social roles and treatment in cancer patients receiving outpatient chemotherapy and radiation therapy.

## ■ Conceptual Framework

The study framework was based on the Donabedian model of healthcare quality assessment[21,22] and the Andragogy of Malcolm Knowles.[23] The algorithm depicts procedures and support that promote a balance between social roles as a "structure" and treatment for quality assessment of nursing care. Results occur with implementation of the intervention according to the algorithm as the "process." These results involve social roles, including employment. Interactions between nursing care providers and patients, as guided by the Andragogy model, influence patients' self-concept, the role of experience, readiness to learn, learning orientation, and motivation to try recommended behaviors or pursue certain goals. Positive interactions may also help patients to achieve harmony between their treatment and social lives, including employment.

## ■ Definition of Terms

- Social role—a function or expected behavior according to an individual's ability and effort, such as a developmental task according to

gender or age, an occupation, or a function or responsibility that occurs situationally in a society or group. In this study, it refers to the roles that a patient has engaged in to date.
- Harmonization—the alleviation and balancing of patients' distress associated with cancer and outpatient treatment with their social roles.
- "Coordination" by nurses—to prepare the environment, including the internal environment (symptom management, motivation to continue treatment, and controlling feelings) and the external environment (affecting people's relationships, roles, economics, and other lifestyle factors) to ensure that cancer patients can continue their social life while undergoing cancer treatment.

# Methods

## Ethical Considerations

The study was approved by the ethics review committee at the university and 3 research institutions with which the authors were affiliated. We obtained written consent from the hospital director and head nurse and physicians and nurses in charge, after explaining the outline, objectives, and content of the study for 5 departments in the 3 hospitals. Eligible patients were provided with verbal and written explanations of the outline, objectives, and content of the study; that the researchers would review their medical records; and that they would be assigned to either an intervention or control group. Before they provided written consent, we explained that participation was voluntary, data would be anonymized, and personal information would be protected.

## Study Design

This was a quasi-experimental study that used a cluster randomized controlled trial design. The control group comprised patients receiving standard nursing care, whereas the intervention group comprised patients receiving the ANI. For the group assignment, we created a list of registered treatment departments at the study sites. The department's nursing manager had 2 blocks for the group variable within a 4-month time period. Then, using a pair of dice, 1 set of 2 blocks was randomly assigned as the intervention group or control group. We randomly assigned participants to the intervention and control groups to ensure that cancer settings, stages, performance status, and treatments would be equivalent between the 2 groups. The study period was from August 3, 2017, to December 3, 2019.

## Settings

Radiation therapy and chemotherapy are the main outpatient cancer treatments in Japan. Therefore, we recruited participants from 2 outpatient radiotherapy and 3 outpatient chemotherapy departments. Among the hospitals in the northern Kanto region of Japan, we selected 3 hospitals (A, B, C) that are recognized as cancer treatment hospitals in the national and prefectural governments. The annual total number of outpatients receiving radiation therapy is 6338 at hospital A and 5531 at hospital B. The annual total number of outpatients receiving chemotherapy is 14 000 at hospital A, 1908 at hospital B, and 4300 at hospital C. Participants recruited people to receive treatment in their respective departments.

## Participants

### SELECTION CRITERIA

Participants were adult patients with cancer receiving chemotherapy or radiation therapy as outpatient care in 3 hospitals in Japan. The selection criteria were as follows: (1) age ≥20 years; (2) initiation of outpatient treatment; (3) Performance Status (PS) of 0 to 1 (0 = ability to perform social activities without symptoms and behave as before cancer onset without restriction, and 1 = mild symptoms, physical work is restricted, but walking, light work, and sitting are possible); (4) being deemed by a nurse to be free of any mental or cognitive disorders; and (5) able and willing to participate in 3 surveys, before treatment (T1), at 3 weeks after treatment was initiated (T2), and at the end of treatment or 2 months after treatment (T3).

### DETERMINATION OF THE REQUIRED SAMPLE SIZE

Sample size was calculated as follows: analysis of variance (ANOVA) power analysis using G*Power[24] with an effect size of 0.4 and power of 0.95 yielded a sample estimate for a total of 130 participants. Considering potential dropouts, we aimed to recruit 150 participants. However, if there were few dropouts and the number of participants reached 130, that lower number of 130 was to be adopted.

## Intervention

The control group received standard nursing support. The nurse asked questions of the participant about medical information such as physical symptoms and allergies, and awareness of cancer treatment plans. The nurse documented symptoms and needs and provided verbal support. The nurse then discussed self-care education related to treatment. During treatment spanning 3 weeks to 2 months, the nurse assessed the grade of adverse events using the Common Terminology Criteria for Adverse Events (CTCAE) version 4.0. The nurse also provided feedback on appropriate self-care behaviors and offered re-education when necessary.

### INTERVENTION GROUP (ANI)

Prior to the start of the study, the researchers trained nurses with more than 5 years of experience who would be involved in the intervention. The training contents included (1) building a relationship, (2) improving the balance between mind and body, and (3) the role of nurses in maintaining social roles including employment. Then, the intervention was practiced and performed with an emphasis on the participant's experience, readiness, and motivation. At the time of a participant's first treatment, the nurse explained to the participant that the nurse would provide support for 2 months and use an ANI figure depicting the path of support of the social roles and treatment being harmonized. The support goal was for the participant to continue the social role. Support elements discussed included treatment knowledge and attitude, symptoms and distress, social role (work, childcare/long-term care), financial counseling, and information literacy. The nurse could involve other cancer nursing specialists and professions when needed.

During treatment from 3 weeks to 2 months, the support goal was to promote harmony between the social role (employment)

and treatment. Discussion targets were adverse events and self-management ability, Distress and Impact Thermometer (DIT) scores, changes in social roles and patients' support systems, and prospects for continuation of treatment (Figure 1). The intervention group received ANI care in addition to the standard care for the 2-month study period.

## Data Collection Method

### ASSESSMENT CRITERIA AND MEASUREMENT TOOLS

Regarding the assessment criteria, we used 2 items related to participants' minds and bodies, 2 items related to social roles, and 1 item related to interprofessional collaboration as primary outcomes.

(1) Distress and Impact Thermometer: The scale developed by Akizuki et al[25] was used to screen for adjustment disorder and depression in cancer patients. The scale is a self-administered questionnaire with 1 item for the distress thermometer and 1 item for the impact thermometer. Distress and obstacles in daily life caused by pain in the preceding week are measured using a scale ranging from 0 to 10. Higher scores indicate greater pain and obstacles. Akizuki et al[25] examined the adjustment disorder and major depression cutoffs of the DIT in 295 cancer patients using the Hospital Anxiety and Depression Scale and *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition* criteria; cutoff points for the detection of adjustment disorders and major depression are "3/4" for the "distress" score and "2/3" for the "impact" score. Sensitivity and specificity were 0.82 and 0.82, respectively.

(2) The number of adverse events: Nurses used the CTCAE to document grades for each adverse event and to record the number of adverse events.

(3) Presence/absence of social roles: Participants were asked if they had a role in the community or at home, and their responses were recorded.

(4) Changes in employment: Participants were asked for presence/absence of changes in employment (resigning/leaving one's job) 2 months after treatment compared with before treatment.

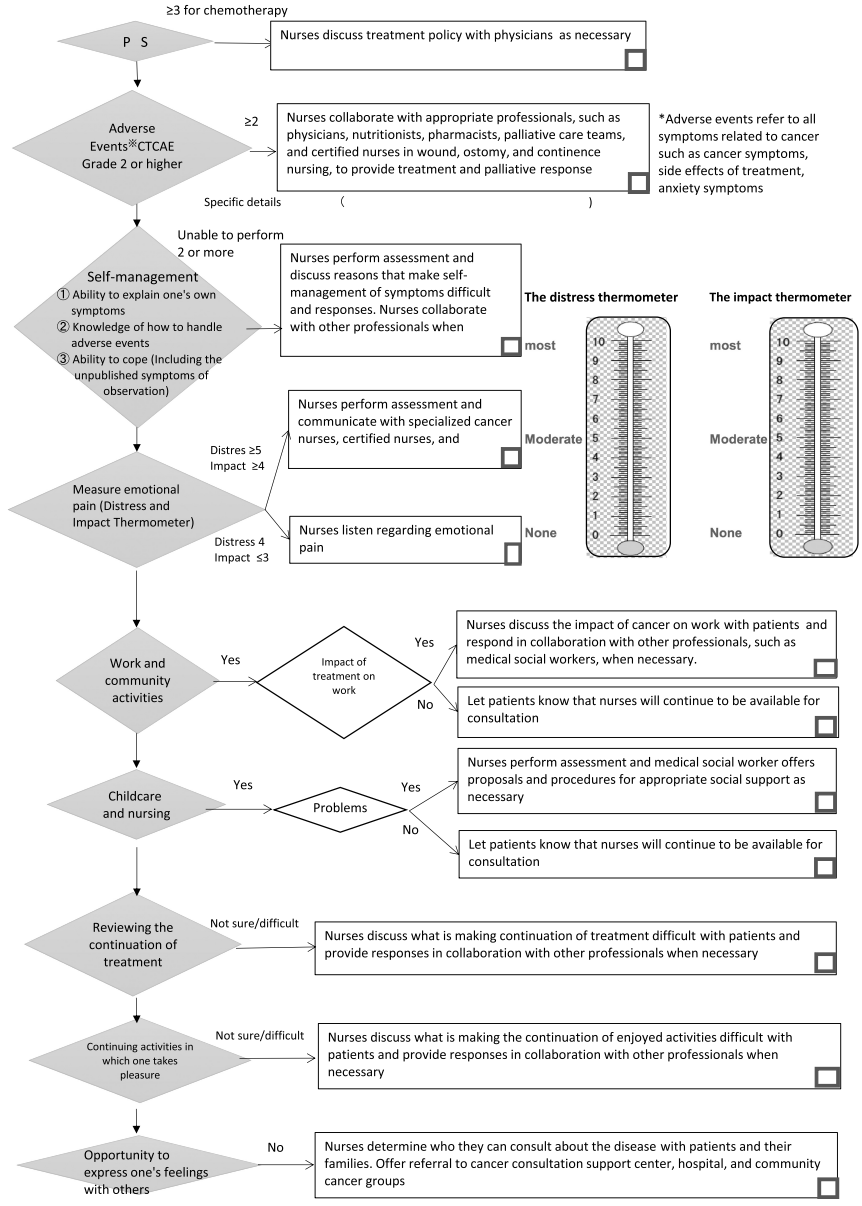


**Figure 1** ■ Algorithm on the examination day (3 weeks to 1 month).

(5) Interprofessional collaboration: We asked if the registered nurse had worked with nursing experts, physicians, and medical social workers in accordance with the needs and situations of participants.

Surveys other than changes in employment were conducted 3 times: T1 (before treatment), T2 (3 weeks after treatment was initiated), and T3 (end of treatment or 2 months after treatment was completed).

## Data Collection Procedure

The study was registered with the UMIN-CTR (trial ID: UMIN000028619) prior to initiation. To ensure that nurses could perform ANI in the exact same steps, we standardized the process using the following instructions: (1) explanation of the importance of autonomy based on the interaction between nurses and participant, (2) preparation of a manual to explain objectives and support methods to nurses, (3) establishment of a preliminary trial period and examination of the steps based on the issues identified in the trial, and (4) inclusion of example questions for participant and judgment criteria (PS ≥3, CTCAE grade ≥3, increased disability to life, changes in treatment content) in the manual.

A database including data regarding DIT, social roles, and employment (resigning and seeking employment) was prepared, and data from the nurses' interviews from each of the 3 time points were entered. For monitoring, 2 researchers per facility confirmed the ongoing eligibility and health status of participants from electronic medical records every 3 or 4 weeks.

## Analytical Methods

Attributes, DIT, the number of adverse events, social roles, and number of interactions with nursing experts, physicians, and medical social workers were analyzed using descriptive statistics. We performed a $t$ test and $\chi^2$ test to compare the 2 groups' attributes and reference values prior to the intervention. To analyze quantitative data, we compared the mean (standard deviation) for each treatment course in both groups. We used a $\chi^2$ test to analyze categorical data, such as social roles and interprofessional collaboration, for both groups.

The distress thermometer scores, the impact thermometer scores (DIT), and the number of adverse events measured at several different times were assessed by using mixed between- and within-subjects ANOVA. We also performed a logistic regression analysis with objective variables of changes in employment status 2 months after the intervention. As explanatory variables, variables such as attributes, DIT, and number of adverse events that showed statistically significant differences in simple regression analysis were used.

We used IBM SPSS Statistics (IBM Community Japan, SYNNEX Japan Corporation) to perform paired analyses, and the significance level was set at $P < .05$. We used G*Power 3.1.9.2 to determine the required sample size.[17,24]

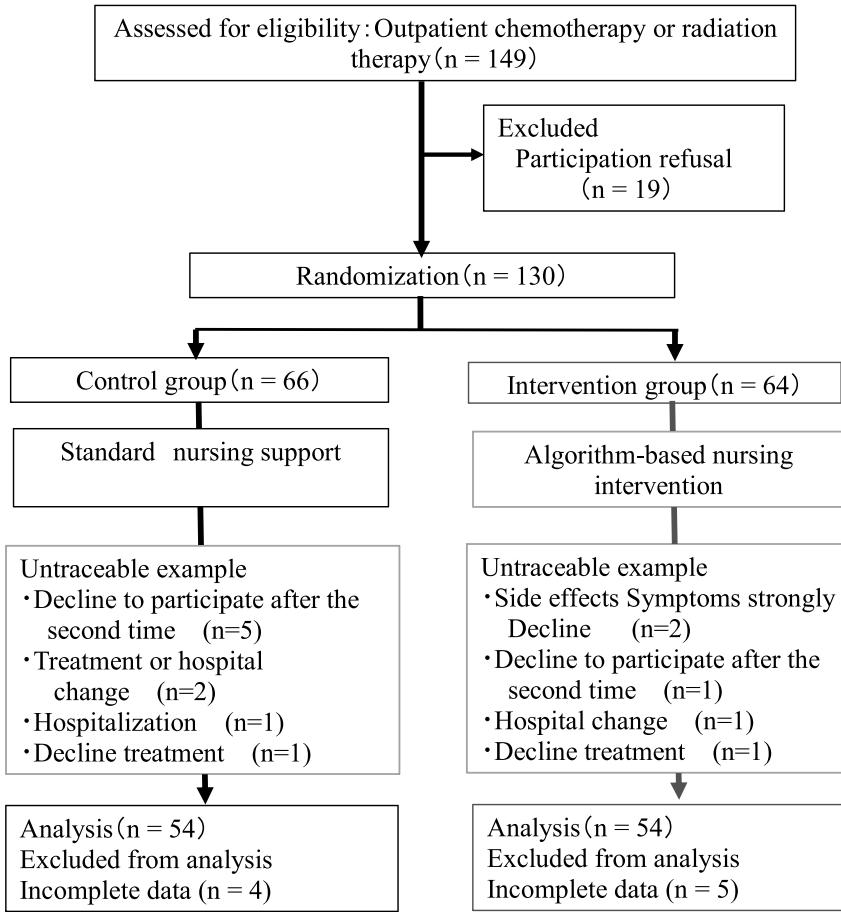


**Figure 2** ■ Flow diagram of study participation.

## ■ Results

### Flow Diagram of Participation

The target number of evaluable participants was 130; a total of 149 patients were invited to participate in the study and received written and verbal explanations of the study. Registration was discontinued when enrolled participants in this study reached the target of 130. Randomization was performed at each department, with 66 participants assigned to standard nursing support (control group) and 64 assigned to ANI (intervention group) (Figure 2). Study participants agreed to participate for 2 months. Fourteen participants did not complete the study for the following reasons: (1) declined to participate after the second time (n = 6); (2) declined because of strong adverse effects (n = 2), treatment or hospital change (n = 3), and hospitalization (n = 1); and (3) declined further treatment (n = 2). The reasons did not differ between the 2 groups except that 2 in the intervention group declined to continue because of adverse effects. Nine participants were excluded from the analysis because of inadequate data. Data from 54 evaluable participants in each group were analyzed.

### Sample

The ages of the participants in the control group ranged from 45 to 81 years (mean, 62.6 [SD, 9.8] years), and those in the intervention group ranged from 33 to 79 years (mean, 61.0 [SD, 11.8] years). The mean ages of the groups did not differ significantly. Participants in the intervention and control groups were selected to match cancer setting, stage, PS, and treatment at sampling, and the results were also similar. There were no significant differences in attributes between groups prior to the intervention (Table 1).

### Algorithm-Based Nursing Intervention Group

Pretreatment ANI: Support was provided for 54 participants. There was a consultation with 6 participants who were not well-informed of or mentally ready for the cancer treatment (11.6%) to further prepare them. The listening technique was used with 11 participants with complaints of pain (20.4%). Of 39 employed participants (72.2%), we provided the intervention for 27 (69.2%) to support them to continue to work. Of 30 participants (55.6%), 19 had a role in nursing care, and 11 were caring for their children and grandchildren. Three participants had a role in childcare, and 12 participants had a role in nursing care. In addition, we provided a consultation on disease for 44 participants (81.5%), advice on information collection for 14 participants (25.9%), and a consultation on finances for 8 participants (14.8%).

### Algorithm-Based Nursing at 3 Weeks and 2 Months After Treatment

At 3 weeks and 2 months after treatment, more than 95% of participants had acquired self-management skills. The work-related intervention was provided for 55% of workers, and the

**Table 1 • Comparison of Backgrounds Between the Control and Intervention Groups at Before Treatment (N = 108)**

| Items | Classification | Control Group n = 54 | | Intervention Group n = 54 | | *P* |
|---|---|---|---|---|---|---|
| | | n | % | n | % | |
| Site of cancer | Urinary system | 10 | 18.5 | 10 | 18.5 | >.999 |
| | Digestive system | 11 | 20.4 | 11 | 20.4 | |
| | Breast cancer | 26 | 48.1 | 26 | 48.1 | |
| | Other | 7 | 13 | 7 | 13 | |
| Stage | 0-II | 29 | 53.7 | 29 | 53.7 | >.999 |
| | III-IV | 25 | 46.3 | 25 | 46.3 | |
| Performance status | 0 | 44 | 81.5 | 44 | 81.5 | >.999 |
| | 1 | 10 | 18.5 | 10 | 18.5 | |
| Treatment | Radiation therapy | 21 | 38.9 | 21 | 38.9 | >.999 |
| | Chemotherapy | 33 | 61.1 | 33 | 61.1 | |
| Relapse | Yes | 9 | 16.7 | 7 | 13 | .588 |
| | None | 45 | 83.3 | 47 | 87 | |
| Living with family | Yes | 49 | 90.7 | 53 | 98.1 | .093 |
| | No | 5 | 9.3 | 1 | 1.9 | |
| Key person | Yes | 53 | 98.1 | 53 | 98.1 | >.999 |
| | No | 1 | 1.9 | 1 | 1.9 | |
| Role | Yes | 48 | 88.9 | 43 | 79.6 | .186 |
| | No | 6 | 11.1 | 11 | 20.4 | |
| Age strata | 20–59 y | 20 | 37.0 | 23 | 42.6 | .243 |
| | 60–74 y | 26 | 48.1 | 24 | 44.4 | |
| | ≥75 y | 8 | 14.8 | 7 | 13.0 | |
| Age, mean (SD), y | | 62.6 (9.8) | | 61.0 (11.8) | | .432 |
| Distress thermometer score, mean (SD) | | 2.0 (1.9) | | 1.5 (2.2) | | .185 |
| Impact thermometer score, mean (SD) | | 1.2 (1.8) | | 0.8 (1.7) | | .325 |
| Adverse events, mean (SD) | | 0.7 (1.2) | | 0.4 (0.8) | | .058 |

intervention for child and nursing care was provided to 50% of caregivers; therefore, approximately half of participants received the intervention. There were no causes that made it difficult to continue treatment, and the prospect of continued treatment was highest at 3 weeks after treatment (94.4%) and decreased to 85.2% at 2 months after treatment. Intervention on the continuation of treatment was 5.6% at 3 weeks after treatment and 11.1% at 2 months after treatment, which showed a slight increase (Table 2).

## Effects of Algorithm-Based Nursing Interventions

### EFFECTS ON MENTAL AND PHYSICAL STATES

*Distress and Impact Thermometer.* The distress thermometer mean score in the control group at T1 was lowest at 1.98 (SD, 1.86) and increased at T2 and T3 to 2.98. In contrast, the intervention group was 1.46 at T1 (SD, 2.16). At T2, it was the minimum value at 0.96 (SD, 2.16) and increased slightly at T3 to 1.09 (SD, 2.16). The difference between the 2 groups was statistically significant at T2 and T3, with the control group having a higher distress score than the intervention group.

The 2-way ANOVA results showed a significant difference between the intervention and control groups ($df$ = 1,106, $F$ = 22.932, $P$ = .0001), whereas treatment period showed no significant difference ($df$ = 2,212, $F$ = 2.549, $P$ = .081). However, there was an interaction between the group and the treatment period ($df$ = 2,212, $F$ = 10.563, $P$ = .0001), confirming that there was a difference in the pattern of T1 to T3 between the control group and the intervention group. Therefore, additional tests were performed for each control group and intervention group using the Bonferroni method. Scores in the intervention group were not significantly different between T1 and T2 and T3. On the other hand, the scores of the control group were significantly higher in T2 ($t$ = −3.026, $P$ < .01) and T3 ($t$ = −5.217, $P$ < .001) than in T1. A significant difference ($df$ = 106, $F$ = 22.932, $P$ = .0001) was observed between the 2 groups and in favor of ANI.

The impact thermometer scores were not significantly different between the pretreatment groups. In the control group, the mean score was lowest at T1 (1.16 [SD, 1.76]) and higher at T2 (2.11 [SD, 2.42]) and T3 (2.24 [SD, 2.05]). In contrast, the mean value in the intervention group was 0.83 (SD, 1.73) at T1, decreased to 0.70 (SD, 1.53) at T2, and slightly increased to 0.88 (SD, 1.69) at T3. The control group had a higher impact thermometer score than that of the intervention group.

The 2-way ANOVA results showed a significant difference between the intervention and control groups ($df$ = 1,106, $F$ = 10.969, $P$ = .001) and treatment period also showed a significant difference ($df$ = 2.212, $F$ = 6.121, $P$ = .003). In group and treatment periods, there also was a significant difference in the interaction ($df$ = 2,212, $F$ = 6.383, $P$ = .002), and differences in patterns were observed. Thus, analysis was performed using Bonferroni's method. As a result, there was a significant difference between the 2 groups ($P$ = .001) and between before and after 2 months of treatment ($P$ = .002) in the period.

**Table 2 • Judgment and Support for the Algorithm Items 3 Weeks and 2 Months After Treatment**

| Item | 3 wk[a] n (%) | 2 mo[b] n (%) |
|---|---|---|
| PS | | |
| ≤2 | 52 (96.3) | 52 (96.3) |
| ≥3 | 2 (3.7) | 2 (3.7) |
| Discuss treatment with a doctor | 2 (3.7) | 2 (3.7) |
| CTCAE | | |
| Grade 1 | 39 (72.2) | 43 (79.6) |
| Grade ≥2 | 15 (27.8) | 11 (20.4) |
| Cooperation with other professionals about adverse events | 5 (9.3) | 7 (13.0) |
| Acquired self-management skills | 54 (100) | 52 (96.3) |
| Intervention on acquiring self-management | 1 (1.9) | 2 (3.7) |
| Active listening regarding emotional pain | 7 (13.0) | 14 (25.9) |
| No. of employees | 38 (70.4) | 29 (53.7) |
| Work impact for workers | 6 (15.7) | 6 (20.7) |
| Work-related intervention for workers | 22 (57.9) | 16 (55.2) |
| No. of people undertaking childcare/nursing care[c] | 29 (53.7) | 25 (46.3) |
| Intervention on childcare/nursing care | 15 (51.7) | 12 (48.0) |
| Awareness of continued treatment | 51 (94.4) | 46 (85.2) |
| Intervention on the continuation of treatment | 3 (5.6) | 6 (11.1) |
| Continuation of favorite things | 49 (90.7) | 51 (94.4) |
| Intervention on continuation of favorite things | 4 (7.4) | 3 (5.6) |
| Opportunity to express one's feelings with others | 46 (85.2) | 50 (92.6) |
| Introduction of a place where you can express your feelings | 8 (14.8) | 2 (3.7) |

Abbreviations: CTCAE, Common Terminology Criteria for Adverse Events; PS, Performance Status.
n = 54 in each group.
[a]Three weeks after treatment.
[b]Two months after treatment.
[c]Indicates the numbers and proportions of workers and individuals providing childcare and nursing care.

**Table 3** • Social Roles at T1, at T2, and at T3 for the Control and Intervention Groups

| | | Control n = 54 | | Intervention n = 54 | | | |
|---|---|---|---|---|---|---|---|
| | | n | % | n | % | $\chi^2$ | *P* |
| Before treatment T1 | Presence | 48 | 88.9 | 43 | 79.6 | 1.729 | .186 |
| | Absence | 6 | 11.1 | 11 | 20.4 | | |
| T2 | Presence | 21 | 38.9 | 20 | 37.0 | 0.039 | .843 |
| | Absence | 33 | 61.1 | 34 | 63.0 | | |
| T3 | Presence | 21 | 38.9 | 22 | 40.7 | 0.038 | .845 |
| | Absence | 33 | 61.1 | 32 | 59.3 | | |

Abbreviations: T1, before treatment; T2, 3 weeks after the treatment; T3, 2 months after the treatment.

#### NUMBER OF ADVERSE EVENTS

The control group had the lowest number of adverse events at 0.72 (SD1.19) at T1, then increased to 2.17 (SD, 1.86) at T2, and remained high at 2.17 (SD, 1.79) at T3. In the intervention group, adverse events were lowest at T1 (0.35 [SD, 0.78]), increased to 1.67 (SD, 1.71) at T2, and decreased slightly to 1.54 (SD, 1.73) at T3.

The number of adverse events was significantly higher in both groups at 3 weeks and 2 months than before treatment. The difference between the mean number of adverse events at each period was significantly lower in the intervention group than in the control group ($df$ = 1,106, $F$ = 6.063, $P$ = .015). In the treatment period, at T1 was the least, followed by T2 and T3, and the longer the treatment period, the significantly higher the number of adverse events ($df$ = 2,212, $F$ = 44.600, $P$ = .0001). No interaction was detected between the group and the treatment period ($df$ = 2,212, $F$ = 0.677, $P$ = .509). Therefore, it was confirmed that the patterns of change in the number of adverse events in both groups were the same and that the intervention reduced the number of adverse events.

#### EFFECTS ON SOCIAL ROLES

Before treatment, 88.8% of the control group and 79.6% of the intervention group had a social role. Three weeks after treatment, the control group was 39.9%, the intervention group was 37.0%, and at 2 months after the treatment, the control group was 38.9%, and the intervention group was 40.7%. The proportion of those with a role was highest before treatment and decreased most at 3 weeks after treatment in both groups. There was no significant difference between the control and intervention groups at any time point (Table 3).

Table 4 shows changes in employment at 2 months after treatment in the control and intervention groups. In total, 20 participants (37.0%) in the control group had either resigned or taken a leave of absence at 2 months after treatment; this number was twice that observed in the intervention group (18.5%), showing a significant difference between groups ($\chi^2$ = 4.573, $P$ < 05). The result of the logistic regression analysis of 8 related items, with changes in employment at 2 months after treatment as the objective variable, was $\chi^2$ = 24.809 $P$ < .01, and the model helped to predict changes in employment. Stages (early or advanced cancers) and control group or intervention group differed significantly between groups (Table 5). That is, patients with advanced cancers were 3.6 times more likely to resign or take a leave of absence than participants with early cancers. The control group rate of resignation or leave was 4.9 times than the intervention group.

### Interprofessional Collaboration

There were not many specialist consultations involved in either group during the study period. There was 1 each at T1, T2, and T3 in the control group, for a total of 3 cases. There were a total of 10 cases in the intervention group, 2 at T1 and 4 cases each at T2 and T3. The only specialists involved in the control group were oncology-certified nurses. However, in the intervention group, T1, T2, and T3 involved 3 groups of specialists: doctors (2), medical social workers (4), and intervention palliative care teams (4).

## ■ Discussion

### Effects of Algorithm-Based Nursing Interventions

The aim of this study was to identify the efficacy of an ANI in promoting a balance between treatment and the social roles of cancer patients receiving outpatient chemotherapy and radiation therapy. To relieve cancer patients' pain and nurture their strengths, the algorithm was centered on building relationships, increasing the balance between mind and body, and personalized coordination of nursing roles to maintain patients' social roles including employment. The DIT scores in the intervention group were significantly lower than those in the control group ($P$ < .001). In addition, 2 months later, 20 participants had resigned or were on leave in the control group (37.0%), twice

**Table 4** • Changes in Employment 2 Months After Treatment for the Control and Intervention Groups

| | Control n = 54 | | Intervention n = 54 | | | |
|---|---|---|---|---|---|---|
| | n | % | n | % | $\chi^2$ | *P* |
| Yes | 20 | 37.0 | 10 | 18.5 | 4.573 | .032 |
| No | 34 | 63.0 | 44 | 81.5 | | |

**Table 5 • Logistic Regression Analysis of Changes in Employment 2 Months After Treatment**

| Item | Odds Ratio | 95% CI | *P* |
|---|---|---|---|
| Age | 0.978 | 0.923–1.037 | .465 |
| Living with family | 0.112 | 0.006–2.106 | .144 |
| Stage (early or advanced cancers) | 3.585 | 1.088–11.817 | .036 |
| Distress thermometer score | 0.909 | 0.562–1.469 | .697 |
| Impact thermometer score | 1.358 | 0.796–2.318 | .262 |
| Interprofessional collaboration | 3.273 | 0.248–43.151 | .368 |
| No. of adverse events | 1.161 | 0.865–1.558 | .320 |
| Control group or intervention group | 4.930 | 1.475–16.482 | .001 |

Abbreviation: CI, confidence interval.

the number in the intervention group, confirming a significant difference ($\chi^2 = 4.573$, $P < .05$). As the efficacy of the ANI was demonstrated, we consider it from the perspectives of effects on the mind and body and effects relating to social roles including employment.

## Effects on the Mind and Body

Many patients receive multidisciplinary care from diagnosis forward. Specific mental illnesses have been reported in 30% to 35% of cancer patients.[26,27] Psychological distress is reported to reduce adherence to treatment,[28] causing problems in treatment decision-making and increasing medical management issues.[29] These findings indicate the importance of distress screening and early intervention in cancer patients.[30]

In this study, outcome indices were the DIT scores. Analysis of variance results for distress thermometer scores in the ANI and control groups indicated that at T3, scores for the ANI were significantly lower relative to those for the control group ($df = 1,106$, $F = 22.932$, $P = .0001$). A similar difference was noted at T2. Impact thermometer scores revealed a similar trend, with impact thermometer scores for the ANI being significantly lower than those in the control group T3 ($df = 1,106$, $F = 10.969$, $P = .001$). Distress thermometer scores at each treatment opportunity yielded scores to prompt active listening and the involvement of other professionals as needed. Likely because of the timely response to patient distress, levels of DIT scores in the ANI group were lower than those in the control group.

The 2019 Distress Management Guidelines (version 3)[31] and the Japanese Government's second phase assessment of its Cancer Control Promotion Plan[12] highlight issues that are not followed up or treated, even with screening. As the current algorithm clearly indicated, postassessment decision and referral criteria compliance enable the early detection of distress and, when necessary, lead to the involvement of other professionals such as palliative care teams. Such screening and involvement of professionals contribute to patients' psychological stability. The intervention also supported the 5 steps of the comprehensive psychosocial screening indicated by Lazenby et al.[32] Moreover, as recommended by the National Comprehensive Cancer Network,[31] the current index is simple and uses a scale ranging from 0 (painless) to 10 (most distressing), suggesting that it could be introduced in facilities with a shortage of nurses.

The number of adverse events was established as an indicator of physical condition. Although the intervention algorithm was the same for both radiation therapy and chemotherapy, the figures were compared, as adverse events differed according to the site of radiation therapy and the drugs used in chemotherapy. Both groups had significantly higher numbers of adverse events at T2 and T3 relative to those observed at T1, indicating the importance of ongoing assessments.

## Effects on Social Roles, Including Employment

The ANI appears to have supported continued employment. That is, relative to pretreatment observations, the number of participants in the intervention group (18.5%) who had resigned or were taking a leave of absence from their employment was significantly lower relative to that in the control group (37.0%; $\chi^2 = 4.573$, $P < .05$) at 2 months after treatment. Furthermore, the odds ratio for resignation or leave of absence in the control group was 4.9 times higher than that in the intervention group.

In Japan, 30% of cancer patients resign voluntarily, and 4% are dismissed.[8,9] Moreover, postcancer employment changes in Japan have been reported, as 22% of men and 8% of women reduced their working hours, and 11% of men and 21% of women resigned from their jobs.[33] Resignation and leave of absence often occur within 6 months of cancer diagnosis, and resignation is particularly common in the early stages of a cancer diagnosis. Cancer survivors are 1.4 times more likely to be unemployed relative to healthy individuals, although this depends on diagnosis.[34] Unemployment rates for cancer survivors vary according to country and sex, with the rates in Europe and North America reported to be 10 and 8 times higher in cancer patients, relative to those observed for individuals without health concerns, respectively.[35]

Research on returning to work following recovery is underway worldwide. In a systematic review conducted by Paltrinieri et al,[36] the employment return rate in Europe ranged from 39% to 77%. In addition, according to a Japanese systematic review of Japanese articles (11 Japanese and 2 English) conducted by Ota et al,[37] this rate ranged from 53.8% to 95.2%. Factors affecting return to work include the impact of cancer on health, cancer progression, and other support.[38,39] However, in recent intervention reviews,[35,36] neither physical/psychological interventions nor interdisciplinary interventions exerted an effect on return to work. Consequently, issues involving research methods, such as participant selection bias, evaluation, and definition ambiguity, have been highlighted. A metaintegration of qualitative research[40] indicated that being employed in a workplace held

different meanings for different individuals and that a multifactor approach to return to work was necessary.[40] Moreover, the majority of research participants are breast cancer patients, and most studies are conducted in Europe or America, with a paucity of research conducted in Asia.[37] Furthermore, no Japanese articles were included in a worldwide intervention review relating to postrecovery return to work,[41] adding to the relevance of the current study examining employment in the Asian region. In addition, as it is difficult to return to work following resignation, cancer patients' continuing to work while receiving treatment and making use of workplace systems and national resources without resigning have benefits for patients.

### Indications for Outpatient Nursing Practice

Use of the present ANI appears to have contributed to lower distress and impact scores during the 2-month period of outpatient chemotherapy and radiation therapy. The role of nurses with regard to adverse events (CTCAE documentation, conversations with physicians, and teaching self-management skill acquisition) was a part of the positive outcomes.

## ■ Limitations of the Trial and Future Challenges

In this study, the predicted sample size for the study was 64 for the ANI and 66 for the control group, but the actual number was 54 for both groups, less than required. Because of strong adverse events, treatment, transfer, and hospitalization, the participation rate was 83.1%, and the dropout rate was 16.9%. In addition, the control group received standard nursing support. The chemotherapy departments of the 2 hospitals included one person with less than 3 years of nursing experience. Therefore, it cannot be denied that there is a difference in the nursing provided to the intervention group and the control group, which may be a source of biases. In the future, a randomized controlled trial design with a larger sample will be needed to establish validity of the ANI.

## ■ Conclusions

Nursing algorithm-based care reduced distress and obstacles to daily life in patients with cancer. As nurses offered timely interventions when adverse events resulting from cancer treatment occurred, employment resignations and leave taking were reduced. The present algorithm provided support for this role in nursing care in outpatient settings. Nurses can contribute to employment support for cancer patients in Japan, which is promoted by the federal government.

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