

The TTM [10] is useful for explaining changes in health behavior and has been used in various programs such as smoking cessation [11], genetic testing for colorectal cancer [12], and mammography adoption [13]. In the TTM, the decisional balance between pros and cons—positive and negative attitudes for the behavior—will account for the state of change observed during five stages: precontemplation, contemplation, preparation, action, and maintenance [10]. We adopted this classification to explain the behavioral intention of patients using CAM in cancer treatment. Moreover, self-efficacy, which acts as a mediating function for the psychological adjustment of cancer patients [14, 15], is an important factor affecting a person's movement from one stage to another.

The TPB [16] examines behavioral intentions based on three major components: the patient's attitude towards the behavior, perceived control, and subjective norms. In cases of cancer patients, attitude towards behavior may include perceived effectiveness of treatment, anxiety regarding side-effects, etc. Perceived control is the individual's perception of the extent to which performance of the behavior is easy or difficult, and is synonymous with the concept of self-efficacy [16]. Subjective norms in cancer CAM include expectation from family members, and norms of medical staff towards the patients.

Our hypotheses are as follows: (i) cancer patients are classified into five stages of CAM use, (ii) the stage of CAM use is explained by TTM and TPB variables, and (iii) perceived control positively correlates with CAM use and mediates between CAM use and psychological adjustment.

## patients and methods

### participants

This study was approved by the institutional review boards of the Kinki Chuo Chest Disease Center, National Kyushu Cancer Center, and National Shikoku Cancer Center. From April 2005 to August 2005, a total of 1100 questionnaires were distributed to patients at each institute. Patients were enrolled in the study after their attending physician assessed if they met the following conditions: were receiving medical treatment through the outpatient or inpatient units at any of the three cancer centers, had an Eastern Cooperative Oncology Group performance status [17] from zero to three, were physically able to fill in the questionnaires by themselves, and had no cognitive impairment. On the questionnaire, we explained the purpose of the study and the fact that returning the questionnaire would be regarded as consent for participation; though we asked the patients to return the questionnaires anonymously.

### measures

For this study, we developed our own questionnaire to examine CAM use in cancer patients (available from the authors). The questionnaire contained 85 items and it took about 20 min to complete. On the cover page of the questionnaire, CAM was defined using same definition of our previous survey [2]: 'as any therapy is not included in the orthodox biomedical framework of care for patients, which includes remedies used without the approval of the relevant government authorities of new drugs after peer review of preclinical experiments and clinical trials regulated by law. Health insurance does not usually cover the cost of CAM, and patients are generally liable for all expenses incurred by CAM use. CAM may include use of natural products from mushrooms, herbs, green tea, shark cartilage, megavitamins, or other special foods, and may

incorporate acupuncture, aromatherapy, massage, meditation, etc'. Additionally, a sheet containing 20 examples of CAM therapies and products was attached to the questionnaire. The first portion of the questionnaire asked for information on the patients' background, including type of disease, age at onset, current age, gender, educational level, economic status, type of cancer treatment, satisfaction with treatment, smoking, drinking, and social support measured by the single item Tangible Social Support Scale [18].

The second part of the questionnaire included items originally designed to evaluate the cancer CAM-specific TTM and TPB variables. To measure the patients' subjective intention with regard to CAM use, we additionally defined cancer CAM use as those 'using any supplements or dietary foods or receiving any therapy that appears to have anticancer effects or auxiliary effect to that of conventional cancer therapy'. Respondents were asked to rate themselves based on the five stages of the TTM [10]: precontemplation ('I have no interest in using CAM'), contemplation ('I have been thinking that I might want to use CAM'), preparation ('I am preparing to use CAM'), action ('I have already used CAM in the last 6 months'), and maintenance ('I have already used CAM for >6 months'). The next section was composed of 27 items measuring TTM and TPB variables. The items were measured on a five-point Likert-type scale that ranged from 'not at all' (1) to 'extremely' (5). They included following five categories: (i) positive attitudes for CAM; (ii) pros; (iii) cons; (iv) expectation from family; and (v) norms of medical staff. The items were developed in our previous study on CAM [2] and another study on dietary food intake [19]. We used 16 from 27 items using confirmatory factor analysis on the current data as structurally valid and reliable items (Table 1). Also, content validity of the all TTM and TPB items in this part was confirmed by experts of two physicians, one psychiatrist and two psychologists.

To assess psychological adjustment, we used the Japanese version [20] of the Hospital Anxiety and Depression Scale (HADS) [21], which has 14 questions on anxiety and depression with each question rated from 0 to 3. The validity and reliability of the Japanese HADS in cancer patients has been confirmed previously [22].

To assess perceived control in patients, we used the Self-Efficacy for Advanced Cancer (SEAC) scale, which was designed to evaluate self-efficacy of cancer patients [23]. The SEAC scale has 18 items with three subscales: symptom coping efficacy, activities of daily living efficacy (ADE), and affect regulation efficacy (ARE). The scale was formatted on an 11-point Likert-type scale ranging from 0 (not at all confident) to 100 (totally confident). The reliability and validity of this scale were also confirmed [23].

Finally, the Japanese version of the MD Anderson Symptom Inventory (MDASI-J) [24] was developed as a brief multiple-symptom assessment scale. It consisted of 13 symptom items [25], and its validity and reliability were confirmed [24]. We used 10 of the 13 physical symptom items for our statistical analyses since the items for distress, sadness, and remembrance were significantly and highly correlated with the HADS total score ( $r = 0.0479$ ,  $P < 0.001$ ;  $r = 0.456$ ,  $P < 0.001$ ;  $r = 0.334$ ,  $P < 0.001$ , respectively).

### statistical analyses

Descriptive analyses were carried out summarizing the participants' backgrounds and scores following psychological measurements. Those with >30% missing values on the questionnaire were excluded from the analyses. The factors predicting stage of CAM use were analyzed through univariate analysis using the analysis of variance. In order to carry out multivariate analyses, we transformed the participants' responses for the stage of CAM use into a numeric scale ranging from 1 to 5 points (1, precontemplation; 2, contemplation; 3, preparation; 4, action; and 5, maintenance), according to a previous study [15]. Next, structural equation modeling (SEM) using the maximum likelihood method was carried out to

Table 1. Items measuring TTM and TPB variables and factor definitions

Items	Factor loadings
<b>Positive attitudes for CAM (Cronbach alpha = 0.83)</b>	
Definition: The items represented the high-perceived availability and importance of CAM use for the patients.	
1. CAM is important to retain physical strength.	0.80
2. Hospital care alone is not enough.	0.68
3. Convenience is an important determinant of starting to use CAM.	0.84
4. The cost of CAM is important.	0.66
<b>Pros (Cronbach alpha = 0.90)</b>	
Definition: The items represented patients' perceived positive outcomes of CAM use.	
5. The use of CAM leads to the cure of disease.	0.90
6. The use of CAM halts the progression of disease.	0.89
7. The use of CAM boosts physical and immune strength.	0.90
8. CAM has fewer side-effects compared with medical care.	0.69
<b>Cons (Cronbach alpha = 0.70)</b>	
Definition: The items represented patients' perceived negative outcomes of CAM use.	
9. The use of CAM has bad influence on medical care.	0.79
10. The use of CAM deteriorates disease.	0.89
11. I am aware of the side-effects of CAM.	0.53
12. I am aware of the dependence liability of CAM.	0.53
<b>Expectation from family (Cronbach alpha = 0.65)</b>	
Definition: The items represented patients' perceived expectations and recommendations from family.	
13. My family/friends believe that I should be actively engaged in the use of CAM.	0.74
14. My use of CAM is influenced by the opinions of my family/friends.	0.65
<b>Norms of medical staff (Cronbach alpha = 0.34)</b>	
Definition: The items represented patients' perceived expectation, recommendation from patients' medical staff, or their norms.	
15. My doctors/nurses believe that I should be actively engaged in the use of CAM.	0.68
16. My use of CAM is influenced by the opinions of my doctors/nurses.	0.30

Fit indices from the confirmatory factor analysis for items and factors indicated above: chi-square (96) = 345.5;  $P = 0.001$ ; GFI = 0.92; AGFI = 0.88; CFI = 0.94; RMSEA = 0.07.

TTM, transtheoretical model; TPB, theory of planned behaviour; CAM, complementary and alternative medicine.

test the model. Because the model needed a parsimonious structure, we used the mean scores of SEAC as 'self-efficacy', the total score of HADS as 'psychological distress', and the mean scores of 10 items of MDASI-J as 'physical symptom'. We conducted all statistical analyses using SPSS (version 14.0) and AMOS (version 5.0.1) software packages.

## results

### response rate to questionnaire

Of the 1100 questionnaires, 750 were given to inpatients and 350 to outpatients. Out of the 651 questionnaires returned

(response rate 59.2%), 521 were valid for statistical analyses. The rest ( $n = 130$ ) were invalid because of the lack of major information such as disease name or stage of CAM use. Moreover, questionnaires from noncancer patients were excluded from the analyses. Thus, the rate of valid replies was 47.4%.

### backgrounds of patients and distribution of CAM use

The participants consisted of 246 males and 270 females, and five unknowns. Table 2 summarizes the demographic and diagnostic information of the participants. For staging, 88 patients (16.9%) were in precontemplation, 226 (43.4%) in contemplation, and 31 (6.6%) in preparation among the 347 CAM nonusers (66.6%), with 71 (13.6%) in action and 103 (19.8%) in maintenance among the 174 CAM users (33.4%). Table 1 also shows the prevalence of the five stages of CAM use categorized by demographic and medical status variables. The prevalence of CAM use in the higher stages, including action and maintenance, was significantly higher in patients who received chemotherapy ( $P < 0.001$ ), those dissatisfied with current conventional treatment ( $P < 0.05$ ), and outpatients ( $P < 0.001$ ).

### psychosocial factors associated with the stages of CAM use

Table 3 shows the mean response and the results of the univariate analyses for psychological variables, physical symptom variables, and social support obtained from patients at each of the five stages of CAM use. There were significant differences amongst patients in the five stages based on pros ( $P < 0.001$ ), cons ( $P < 0.001$ ), positive attitude for CAM ( $P < 0.001$ ), and expectation from family members ( $P < 0.001$ ). There was a slightly higher response on ADE ( $P < 0.10$ ) in patients who were in the action and maintenance stages.

### structural model for stages of CAM use

We carried out SEM by first selecting 14 variables in the initial model because they were observed to be significant predictors in the univariate analysis or were essential components for the TTM and TPB theories: use of chemotherapy, period from diagnosis, whether need for treatment was met, treatment place, stage of CAM use, psychological distress, pros, cons, positive attitude, expectation from family members, norms of medical staff, self-efficacy, psychological distress, physical symptoms, and social support. Next, we drew all paths according to the results of the correlation analysis. Since there was a significantly strong correlation between the pros and a positive attitude ( $r = 0.80$ ,  $P < 0.001$ ), and since the explanation by the TTM is given a priority for our purposes, we dropped positive attitude from the initial model. We repeated the SEM and sequentially dropped paths that were not significant until all the paths in the model became significant ( $P < 0.05$ ). The variable 'met need for treatment' was dropped from the model because all the paths from this variable became not significant.

Figure 1 represents the final model. The fit indices for this model were excellent and included the following: chi-square



Table 2. Patients' background and CAM use stage

	Total	Precontemplation		Contemplation		Preparation		Action		Maintenance		P (v <sup>2</sup> test)
	n	n	%	n	%	n	%	n	%	n	%	
Total	521	88	16.9	226	43.4	33	6.3	71	13.6	103	19.8	
Age years												
>60	262	47	17.9	120	45.8	13	5.0	31	11.8	51	19.5	0.446
≤60	253	40	15.8	105	41.5	19	7.5	40	15.8	49	19.4	
Gender												
Male	270	43	15.9	112	41.5	22	8.1	35	13.0	58	21.5	0.336
Female	246	45	18.3	110	44.7	11	4.5	36	14.6	44	17.9	
Education												
High school	318	50	15.7	141	44.3	7.2	7.2	46	14.5	58	18.2	0.561
Posthigh school	174	34	19.5	67	38.5	10	5.7	25	14.4	38	18.2	
Period from diagnosis												
≤1 year	261	56	21.5	118	45.2	20	7.7	46	17.6	21	8.0	0.000
>1 year	246	29	11.8	102	41.5	10	4.1	25	10.2	80	32.5	
Conventional treatment												
Chemotherapy	393	58	14.8	158	40.2	28	7.1	61	15.5	88	22.4	0.001
Nonchemotherapy	122	27	22.1	66	54.1	5	4.1	10	8.2	14	11.5	
Treatment met patient's needs												
Yes	371	72	19.4	161	43.4	18	4.9	49	13.2	71	19.1	0.045
No	150	16	10.7	65	43.3	15	10.0	22	14.7	32	21.3	
House income												
≥£7 000 000	113	17	15.0	48	42.5	5	4.4	13	11.5	30	26.5	0.438
<£7 000 000	334	53	15.9	144	43.1	23	6.9	50	15.0	64	19.2	
Treatment place												
Inpatient ward	360	67	18.6	167	46.4	27	7.5	53	14.7	46	12.8	0.000
Palliative care unit	24	2	8.3	8	33.3	5	20.8	3	12.5	6	25.0	
Outpatient clinic	161	21	13.0	59	36.6	6	3.7	18	11.2	57	35.4	
Cancer												
Lung	190	28	14.7	69	36.3	11	5.8	34	17.9	48	25.3	0.137
Breast	55	11	20.0	30	54.5	4	7.3	4	7.3	6	10.9	
Gastrointestinal	79	13	16.5	40	50.6	6	7.6	10	12.7	10	12.7	
Gynecological	61	8	13.1	28	45.9	2	3.3	7	11.5	16	26.2	
Other	121	24	19.8	54	44.6	9	7.4	13	10.7	21	17.4	

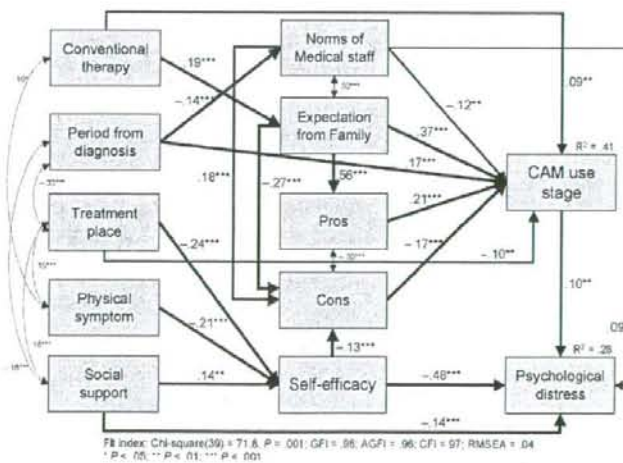


Figure 1. Structural model for the stage of CAM use and psychological adjustment.

Table 3. Descriptive data and ANOVA: mean comparison among CAM use stages

Measure	Precontemplation		Contemplation		Preparation		Action		Maintenance		P (F test)
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	
TTM components*											
Pros	20.74	1.09	20.28	0.84	0.52	0.64	0.67	0.86	0.52	0.79	0.000
Cons	0.31	0.93	0.30	0.90	0.17	0.91	20.58	0.83	20.52	1.03	0.000
TPB components*											
Positive attitude	20.84	0.99	20.27	0.90	0.58	0.62	0.61	0.77	0.59	0.73	0.000
Expectation from family member	20.71	0.81	20.35	0.80	0.58	0.85	0.63	0.93	0.64	0.88	0.000
Norms of medical staff	20.10	1.06	0.05	0.92	0.08	1.11	0.12	0.95	20.14	1.09	0.335
Self-efficacy											
ARE	60.34	26.28	57.93	23.33	57.72	23.51	64.82	20.34	61.17	19.83	0.241
SCE	54.80	28.38	53.61	23.16	54.48	26.21	61.21	20.97	57.92	21.98	0.167
ADE	66.33	27.48	64.83	25.44	67.26	25.47	72.85	19.00	70.89	23.75	0.097
Total	60.49	26.44	58.79	23.18	59.82	23.87	66.30	19.01	63.33	20.68	0.139
HADS											
Anxiety	5.58	3.65	5.71	3.86	6.02	4.11	5.58	4.31	6.14	3.90	0.335
Depression	5.42	3.29	5.83	3.39	6.13	3.82	5.66	4.11	6.48	4.04	0.841
Total	11.00	6.26	11.54	6.66	12.15	7.30	11.24	8.05	12.62	7.26	0.533
Physical symptom											
Pain	29.01	33.68	28.13	31.88	37.42	32.66	32.50	34.09	23.70	30.61	0.227
Lack of appetite	33.61	34.56	27.41	30.30	31.43	29.15	32.35	32.97	24.00	30.48	0.219
Disturbed sleep	33.73	33.52	27.63	27.72	29.03	24.81	34.06	29.42	32.60	32.27	0.335
Nausea	20.95	32.51	22.57	30.67	18.71	27.78	22.65	32.07	20.10	32.28	0.937
Fatigue	38.10	29.76	32.80	27.59	37.74	28.37	34.06	30.06	37.92	29.71	0.461
Dyspnea	23.37	29.81	18.62	26.40	19.67	19.91	21.32	27.64	26.02	29.17	0.235
Numbness or tingling	28.80	32.25	25.79	29.21	27.33	30.16	28.26	31.85	30.30	33.53	0.800
Drowsy	34.88	26.86	28.69	26.86	37.00	26.67	31.76	26.26	35.54	27.62	0.140
Vomiting	20.85	32.93	18.97	30.53	16.00	28.96	20.00	30.71	20.70	31.92	0.944
Dry mouth	30.49	31.70	27.16	28.82	31.67	30.41	24.93	27.15	28.63	28.91	0.725
Physical symptom <sup>b</sup>											
Total	29.59	22.87	25.90	21.62	28.73	18.17	28.38	21.80	28.10	22.53	0.695
Social support											
Tangible assistance	6.09	5.27	5.57	4.37	6.71	4.90	6.12	3.85	5.12	2.88	0.307

\*Z score.

<sup>b</sup>Average score among 10 physical symptom variables.

ANOVA, analysis of variance; CAM, complementary and alternative medicine; SD, standard deviation; TTM, transtheoretical model; TPB, theory of planned behaviour; ARE, affect regulation efficacy; SCE, symptom coping efficacy; ADE, activity of daily living efficacy; HADS, Hospital Anxiety and Depression Scale.

(39) = 71.8,  $P = 0.001$ ; Goodness of fit index = 0.98; Adjusted goodness of fit index = 0.96; Comparative Fit Index = 0.97; and Root Mean Square Error of Approximation = 0.04.

Overall, the final model accounted for 41% of the variance in the stage of CAM use and 28% of the variance in psychological distress. The parameter with the highest value that explained the stage of CAM use was expectation from family members ( $\beta = 0.37$ ,  $P < 0.001$ ). Furthermore, norms of medical staff and pros and cons all had significant direct effects on the stage of CAM use ( $\beta = -0.12$ ,  $P < 0.01$ ;  $\beta = 0.21$ ,  $P < 0.001$ ; and  $\beta = 20.17$ ,  $P < 0.001$ , respectively). The demographic and medical status variables that significantly explained the stage of CAM use included receiving chemotherapy ( $\beta = 0.09$ ,  $P < 0.01$ ), period from diagnosis ( $\beta = 0.37$ ,  $P < 0.001$ ), and treatment place ( $\beta = 20.10$ ,  $P < 0.01$ ). The parameter with the highest value that explained psychological distress was self-efficacy ( $\beta = 0.17$ ,  $P < 0.001$ ). Moreover, social support significantly affected psychological distress ( $\beta = 20.14$ ,  $P < 0.001$ ).

Finally, the stage of CAM use significantly, though only partially, affected psychological distress ( $\beta = 0.10$ ,  $P < 0.01$ ).

## discussion

Our survey revealed that 33% of the participants used CAM as a replacement or an adjuvant to conventional cancer treatment. The rate of CAM use in this study approximately corresponded to the rate in a previous study [26], but was lower than the rate observed in a Japanese national survey [2]. This is likely due to the fact that our sample consisted of a much smaller number of patients from the palliative care unit ( $n = 24$ , 4.7%) compared with the previous study ( $n = 289$ , 9.3%). When we grouped participants into the five TTM stages of CAM use, the contemplation stage had the largest population ( $N = 226$ , 43.4%). Although these participants did not use CAM, they expressed interest in using it in the near future. Therefore, we concluded that a majority of our participants were potential CAM users.



Using SEM, we determined that 41% of the variance in advance of the CAM use stage was mainly due to the following TTM and TPB variables: expectation from family (positive), pros (positive), norms of medical staff (negative), and cons (negative). Three demographic and medical status variables were statistically significant in explaining CAM use, but their size was smaller than the other psychological variables. Therefore, we concluded that psychological variables are important factors promoting CAM use. With psychological variables, the pattern in which pros were positive predictors and cons were negative predictors of a person's stage, is consistent with the theoretical postulation of the TTM [10]. The most frequent pro notion regarding CAM was that it 'boosts physical and immune strength', while the most frequent con was that it had 'unpleasant side-effects' ['agree' and 'strongly agree' response: N = 272 (53%); N = 187 (38%), respectively]. Thus, beliefs regarding the positive outcome of CAM were strong motivations for CAM use, but patients simultaneously worried about the adverse effects. Therefore, if the patients' perceived balance between the pros and cons of CAM was to be changed by acquiring new information on CAM—e.g. the positive effect of a certain CAM product was empirically proven by a clinical trial—many patients in the contemplation stage would likely then use CAM. Therefore, it is important to provide evidence based and easy to understand information on CAM use in a systematic way, such as guidebooks or web resources, and to develop clinical guidelines on CAM use.

Another unique feature of CAM use that we determined is that the expectation from family in TPB explained the largest part of the variance in the CAM use stage. Previous studies have reported that family and friends of cancer patients generally provided information, supported the decision, or recommended the use of CAM [2, 27, 28], and that CAM users were not autonomous problem solvers [29]. Therefore, our result makes much clear of the critical role that patient recognition of family pressure plays during the decision-making process for CAM use.

Previous studies have indicated that the use of CAM was a marker of bad psychological adjustment [6] and had positive effects on patients' sense of control [30]. On our results, progressed stage of CAM use significantly but not strongly predicted psychological distress, which was mainly explained by self-efficacy, that is, perceived control, and it did not directly explain CAM use stage and mediated by cons. In summary, CAM use did not directly provide perceived control to patients but a little worse psychological adjustment. We could not obtain the evidence that perceived control had strongly mediated the relationship between CAM use and psychological adjustment.

The limitations to this study include the cross-sectional design and sample. Use of SEM could have made clear of multiple relationships among variables in the cross-sectional design. This study also used a convenient sample recruited from three cancer centers. In order to obtain epidemiological details of the CAM use, we need to carry out a large sample prospective study confirming the results of this study. The response rate of our study, 59% was slightly higher than that of our previous national survey, 57% [2]. However, the valid

response rate was 47%, mainly due to the missing of a single item for stage of CAM use. These indicated that sampling was valid, however it will limit generality of our results. It might be needed to improve assessment for stage of CAM use in the questionnaire.

In conclusion, this study using two psychological model provided strong evidence that the existence of psychologically induced potential CAM users and psychological variables including positive attitude for CAM use and perceived family expectation greatly influence CAM use in cancer patients.

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## Discrimination between worry and anxiety among cancer patients: development of a brief cancer-related worry inventory

Kei Hirai<sup>1,2,\*</sup>, Mariko Shiozaki<sup>3</sup>, Hiroko Motooka<sup>4</sup>, Hirokazu Arai<sup>5</sup>, Atsuko Koyama<sup>6</sup>, Hiroki Inui<sup>7</sup> and Yosuke Uchitomi<sup>8</sup>

<sup>1</sup>Center for the Study of Communication Design, Department of Psychology and Behavioral Sciences, Graduate School of Human Sciences, Japan

<sup>2</sup>Department of Complementary and Alternative Medicine, Graduate School of Medicine, Osaka University, Osaka, Japan

<sup>3</sup>The Japan Society for the Promotion of Science, Japan

<sup>4</sup>Graduate Schools of Clinical Psychology, Kansai University of Welfare Sciences, Japan

<sup>5</sup>Department of Health Psychology, Osaka University of Human Sciences, Japan

<sup>6</sup>Department of Psychosomatic Medicine, Kinki University School of Medicine, Japan

<sup>7</sup>Department of Surgery, Kinki University School of Medicine, Japan

<sup>8</sup>Research Center for Innovative Oncology, National Cancer Center Hospital East, Japan

\*Correspondence to:

Graduate School of Human Sciences, Osaka University, 1-2 Yamadaoka, Suita, Osaka 565-0871, Japan.  
E-mail: khirai@grappo.jp

### Abstract

**Objectives:** A psychometric scale for assessing cancer-related worry among cancer patients, called the Brief Cancer-Related Worry Inventory (BCWI), was developed.

**Methods:** A cross-sectional questionnaire survey for item development was conducted of 112 Japanese patients diagnosed with breast cancer, and test-retest validation analysis was conducted using the data from another prospective study of 20 lung cancer patients. The questionnaire contained 15 newly developed items for cancer-related worry, the Hospital Anxiety and Depression Scale, The Impact of Event Scale Revised, and the Medical Outcomes Study Short Form-8.

**Results:** Exploratory factor analysis of the 15 items yielded a 3-factor structure including (1) future prospects, (2) physical and symptomatic problems and (3) social and interpersonal problems. A second-order confirmatory factor analysis identified a second-order factor called cancer-related worry and confirmed the factor structure with an acceptable fit (chi-square (df = 87) = 160.16,  $P = 0.001$ ; GFI = 0.83; CFI = 0.92; RMSEA = 0.09). The internal consistency and test-retest reliability were confirmed with the lung cancer sample. Multidimensional scaling found that cancer-related worry is separate from anxiety, depression, and posttraumatic stress disorder (PTSD) symptoms.

**Conclusion:** Our study succeeded in developing and confirming the validity and reliability of a BCWI. The study also confirmed the discriminable aspects of cancer-related worry from anxiety, depression, and PTSD symptoms.

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**Keywords:** worry; anxiety; stressor; cancer; oncology

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### Introduction

Being diagnosed with cancer is itself a major stressful event for cancer patients, and they subsequently experience other kinds of stressful events related to cancer and its treatment. As the first reaction to these negative events and cancer-related experiences, a number of cancer patients experience feelings of anxiety, and anxiety sometimes becomes a clinically important problem in its own right [1].

Anxiety in cancer patients is a concept for negative state of mind and has been defined as intrusive and unpleasant anxious thoughts; often

involving recurrence of disease, death, or disability; and causing considerable disruption in concentration, decision-making, sleep, and social functioning [1]. Several anxiety-related measurement scales have been frequently used to assess anxiety-related moods or emotions of cancer patients. They include the State-Trait Anxiety Inventory and the Hospital Anxiety and Depression Scale (HADS). These scales mainly measure the patient's somatic symptoms caused by autonomic nervous activities, which correspond to a patient's level of anxiety, but do not evaluate what the patient is anxious or worried about. Therefore, the contents and types of causes, that is, the stressors that evoke anxiety have

not been clarified. In addition, there is a clinical need to evaluate the contents of patients' anxious status with convenient means to detect patients' needs or preferences in order to design individualized care for the patients.

For that purpose, several studies to evaluate stressors that would make the patients anxious have been undertaken in order to define unmet needs or concerns. The studies of unmet needs for cancer patients addressed psychological factors such as fear, anxiety, information about the medical system, physical factors, activity of daily living, disease itself, side effects of treatment, human relations, social support, social issues, and sexual issues [2-5]. The studies revealed types and contents of concerns of cancer patients. Domains of general concerns for cancer patients were cancer itself, disability, family, work, economic status, loss of independence, physical distress, psychological distress, medical uncertainty, and death [6-12].

The term worry has been used as a cardinal symptom in general anxiety disorder in *Diagnostic and Statistical Manual of Mental Disorders-Revised* (DSM-III-R) [13]. According to Wells' metacognitive theory, worry is a chain of catastrophic thoughts that are predominantly verbal, consists of the contemplation of potentially dangerous situations and of personal coping strategies and can become the focus of an individual's concern [14]. Therefore, worry is a predominantly cognitive activity, [15] which is characterized by negative thought and images about the outcome of events, particularly concerns about the future, and a part of anxiety but discriminable from it. In the cancer literature, worry indicates the fear of having cancer; several studies of cancer worry were investigated for cancer screening settings [16,17] such as mammography [18], ovarian cancer [19], and prostate cancer screening [20]. There are few studies concerning worry in cancer patients after their diagnosis. It was reported that the level of prediagnostic intrusive thoughts would provide a significant, useful, and practical method for clinicians to identify in advance those patients likely to worry excessively following a diagnosis of cancer [21]. A worry content scale was developed to assess multiple dimensions of worry in cancer patients [22].

However, the conceptual difference between worry and anxiety is unclear, especially from empirical perspectives, and it is necessary to confirm the validity of discrimination between the measures for worry and for anxiety. Therefore, we performed a cross-sectional study of breast cancer patients and a prospective observational study of lung cancer patients with the following aims: (1) to develop a scale to assess the variation in contents and strength of cancer-related worry thoughts; (2) to confirm the validity and reliability of the scale;

and (3) to test discrimination between cancer-related worry and anxiety.

## Methods

### Participants

This study involved consecutive sampling and was composed of two different samples, which were breast cancer patients after surgery for the main phase of the study and lung cancer patients after surgery for the validation phase. The work was carried out in two university hospitals located in Osaka prefecture, Japan from July 2005 to August 2005 (breast cancer) and from February 2006 to April 2006 (lung cancer). Before initiation of this survey, the study protocol was examined and approved by the institutional review boards.

Both samples of breast cancer and lung cancer included patients with an Eastern Cooperative Oncology Group performance status of 1 or 2 and those who underwent surgery. On the face sheet of the questionnaire for the development phase, a single sentence explained that ethical notification and return of the questionnaire were regarded as consent to participate in our study, and patients were asked to return the questionnaires anonymously. For validation phase, we obtained written informed consent for participation in the study. Each patient was asked to complete two questionnaires in one month.

### Instrument development

The questionnaire for cancer-related worry was developed by the authors and called the Brief Cancer-Related Worry Inventory (BCWI). We pooled items to describe patients' worries, concerns, unmet needs, and stressors by review of related articles [2-12]. The main domain of the items were *cancer itself, disability, effect of cancer treatment, side effects, physical distress, psychological distress, change of appearance, sexual issues, medical uncertainty, death, social support from family and medical staff, work, and economic status*. As we intended to develop a brief and clinically useful instrument, the developed items underwent intensive review of their content and clinical validity and modification of their verbal expressions by an oncologist, a nurse manager of a cancer ward, two psychiatrists, and two psychologists who were experienced in psycho-oncology practice and research. Finally, 15 items were selected through this procedure (see Table 2). The participants were asked to rate their degree of worry about the 15 items on an 11-point Likert-type scale, ranging from 0 (not at all worried) to 100 (extremely worried).



## Measures

We used the Japanese version [23] of the HADS [24] to assess patients' depression and anxiety. The HADS has 14 items in two question groups, one each on anxiety and depression, and each question is rated from 0 to 3.

The Japanese version of the Impact of Event Scale-Revised (IES-R) [25,26] was assessed for Posttraumatic Stress Disorder (PTSD) symptoms based on DSM-IV criteria. Respondents were asked to rate each item in relation to their cancer and its treatment, referring to their condition over the previous seven days. IES-R assesses three dimensions of PTSD symptoms: avoidance, intrusion, and hyperventilation.

Finally, the Japanese version of the Medical Outcomes Study Short Form-8 (SF-8) [27,28] was used to evaluate health-related quality of life. Each of the 8 items assesses a different dimension of health: general health, physical functioning, role

physical, bodily pain, vitality, social functioning, mental health, and role emotional. The SF-8 provides summary scores for Physical Component Scales (PCS) and Mental Component Scales (MCS). Scores from each item or summary measurements range from 0-100, with higher scores indicating better health.

## Statistical analyses

Descriptive statistics were calculated for 15 items for the BCWI. As no largely skewed items were found, we performed an exploratory factor analysis using the maximum likelihood method and the promax rotation methods. After extracting factor structure, we performed the confirmatory factor analysis using the maximum likelihood method to test whether our factor structure fit the data. After calculating total scores of each subscale of the cancer-related worry scale, the correlation analyses were performed to evaluate convergence and validity of discrimination among subscales of cancer-related worry, HADS, IES-R, and SF-8. We used multidimensional scaling analysis based on the Euclidean distance model of stimulus configuration of measures to graphically describe and cluster multiple relations and similarities among cancer-related worry, HADS, and IES-R using their standardized scores. This statistical method can visualize similarities of endorsements by making a matrix of correlation coefficients. Kruskal's stress values were used as a badness-of-fit measure, and the two dimensional solution was adopted because of its simplicity, and ease of interpretation. To test the reliability of the BCWI, we calculated Cronbach's alpha on both the main and validation phase data and intra-class correlation coefficients of scores in the validation phase for test-retest reliability. We conducted all statistical analyses using the SPSS software package

Table 1. Patients' background

	Development breast cancer N = 109		Validation lung cancer N = 20	
Age (years)				
Mean	54.5		65.6	
SD	11.4		8.8	
Gender				
Male	43	15.9%	16	41.5%
Female	45	18.3%	4	44.7%
Time since diagnosis (months)				
Mean	31.3		5.8	
SD	38.6		12.5	
Stage				
I	56	51.4%	12	60.0%
II	53	48.6%	0	0.0%
III			3	15.0%
Other			5	25.0%
Chemotherapy	58	14.8%	0	0.0%

Table 2. Factor loadings and mean score of Brief Cancer-Related Worry Inventory

	Factor 1 (future prospects)	Factor 2 (physical and symptomatic problems)	Factor 3 (social and interpersonal problems)	Mean	SD
(1) About whether cancer might get worse in the future	0.87	-0.09	0.05	53.70	31.70
(2) About cancer itself	0.84	0.09	-0.13	71.30	29.03
(3) About effect of current treatment	0.75	-0.26	0.27	38.50	28.99
(4) About life and death of oneself	0.69	0.21	-0.07	50.80	30.71
(5) About how to cope with cancer situation	0.57	0.32	0.05	41.00	25.35
(6) About mental status	0.55	0.34	-0.12	41.00	27.72
(7) About physical symptom	0.10	0.74	-0.08	37.60	29.93
(8) About side effect of cancer treatment	0.10	0.63	0.01	41.90	29.97
(9) About change of appearance	-0.03	0.62	0.23	37.80	31.19
(10) About sexual issues	-0.07	0.42	0.16	14.20	20.81
(11) About relationships with family members	-0.03	-0.06	0.88	18.40	25.50
(12) About doing job or house work	-0.18	0.34	0.65	31.80	31.19
(13) About relationships with medical staff	0.30	-0.03	0.48	20.00	23.01
(14) About the future of family members	0.35	0.04	0.42	39.50	30.74
(15) About economic problems	0.07	0.37	0.40	38.40	34.03

(version 11.0), except for the confirmatory factor analysis for which we used the EQS software package (version 5.6).

## Results

### Backgrounds of patients and distribution

Patients who satisfied the inclusion criteria and consented for enrollment in this study returned 112 responses in the development phase and 20 responses in the validation phase. Because 3 responses in the development phase were excluded due to more than 30% missing values, 109 responses in the development phase and 20 responses in the validation phase were finally analyzed. Table 1 summarizes the backgrounds of the patients in the development and validation phases.

### Descriptive statistics of BCWI

Table 2 shows descriptive statistics of the 15 items in the BCWI. The item that had the highest mean score was 'worry for cancer itself' ( $M = 71.3$ ), followed by 'worry for recurrence and metastasis' ( $M = 53.7$ ) and 'worry for future life and death' ( $M = 50.8$ ). The lowest scoring item was 'worry for sexual problems' ( $M = 14.2$ ). The next lowest items were 'worry for family relationships' ( $M = 18.4$ ) and 'worry for relationships with medical staff' ( $M = 20.0$ ).

### Factor structure of the BCWI

The exploratory factor analysis of the 15 items yielded a 3-factor structure. This solution was adopted because it was the only interpretable factor structure and its eigenvalue was  $>1.0$ . The subscales were interpreted as (1) future prospects, (2) physical and symptomatic problems, and (3) social and interpersonal problems (Table 2). We then adopted a second-order factor structure with 15 items and 4 factors including a second-order factor, cancer-related worry, due to moderate correlations among 3 factors, consistency with the hypothesized concepts, and clinical validity for a confirmatory factor analysis. The fit indices for this model were acceptable: chi-square ( $df = 87$ ) = 160.16,  $P = 0.001$ ; GFI = 0.83; CFI = 0.92; RMSEA = 0.09. Figure 1 presents the factor structure of BCWI.

### Internal consistency and test-retest reliability of BWCI

Table 3 summarizes the internal consistency (Cronbach's alpha coefficients) and test-retest reliability of the BWCI on the data obtained from the test-retest phase for lung cancer patients. The

BWCI had excellent internal consistency for both breast cancer and lung cancer samples and moderate and substantial test-retest reliability for the lung cancer sample.

### Validity of the BCWI and discrimination form anxiety

Table 4 shows the correlations among BCWI, HADS, IES-R, and SF-8. There are significant and moderate correlations between subscales of BCWI, HADS, and IES-R ( $r = 0.27-0.59$ ,  $P < 0.01$ ), weak correlations between subscales of BCWI and PCS of SF-8 ( $r = -0.28$  to  $-0.19$ ,  $p < 0.05$ ), and moderate correlations with MCS ( $r = -0.42$  to  $-0.43$ ,  $P < 0.001$ ).

Figure 2 shows the structure of worry, anxiety, depression, intrusive, avoidance, and hyperarousal in BCWI, HADS, and IES-R using multidimensional scaling. The horizontal dimension and the vertical dimension successfully discriminate BCWI, HADS, and IES-R. The subscales of IES-R are located in the area defined by positive values both on the horizontal and vertical dimensions. The subscales of HADS were located in the negative area on the horizontal dimension and the positive area on the vertical. Three subscales of BCWI are located in the negative area on the vertical axis and the area near zero on the horizontal dimension. Kruskal's stress value ( $= 0.14$ ) and proportion of variance of data ( $= 0.89$ ) indicated that this solution was valid and accounted for more than 89% of the variance. The analysis showed that cancer-related worry is identifiable from anxiety, depression, and PTSD symptoms.

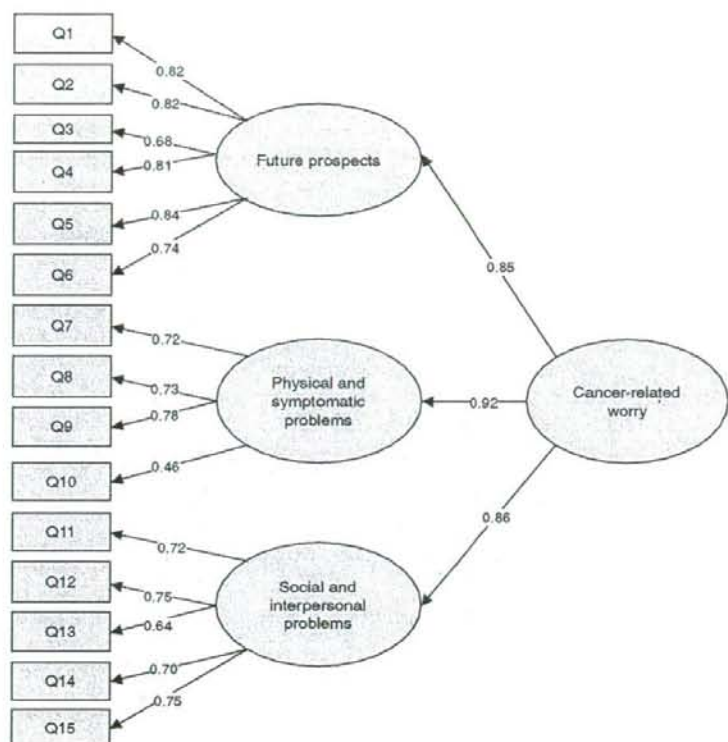
## Discussion

We have successfully developed a brief instrument for the measurement of cancer-related worry of cancer patients (BCWI). The psychometric properties of the scale are acceptable. The reliability was shown by excellent internal consistency (overall Cronbach's alpha coefficient = 0.87) and fair test-retest reliability (intra-class correlation coefficient = 0.69). Construct validity was established by confirmatory factor analysis. In addition, the 15 items of the BCWI did not have any ceiling or floor effects. The feasibility of the scale was established with two different samples, breast cancer and lung cancer patients. Therefore, the BCWI has necessary and sufficient constructs for a useful compact scale with reliability and validity.

The scale has three subscales, namely future prospects, physical and symptomatic problems, and social and interpersonal problems. The themes of the subscales were consistent with previously identified domains in the concern or unmet need studies [2-12]. The future prospect subscale repre-



## Development of a scale for cancer-related worry



**Figure 1.** The factor structure of BCWI. Parameter estimates are standardized. Model Fit index Chi-square(87) = 160.16,  $P = 0.00$ ; GFI = 0.83; CFI = 0.92; RMSEA = 0.09. Numbers of items correspond to those in Table 2

**Table 3.** Reliability of the Brief Cancer-Related Worry Inventory

	Cronbach alpha coefficients <sup>a</sup>	Cronbach alpha coefficients <sup>b</sup>	Test-retest ICC <sup>c</sup>
Future prospects	0.90	0.86	0.75
Physical and symptomatic problems	0.77	0.69	0.53
Social and interpersonal problems	0.83	0.75	0.54
Cancer-related worry	0.87	0.92	0.69

<sup>a</sup>Development phase (breast cancer).

<sup>b</sup>Validation phase (lung cancer).

<sup>c</sup>Intra-class correlation coefficients.

sents the worries for future events, outcomes, or uncertainty. The mean scores of the items in this subscale were higher than that of other subscales. A previous study reported that uncertainty of hospitalized patients was correlated with stress [29]. These studies indicated that future prospects including uncertainty and perceived negative outcomes or consequences of cancer comprise a central concept of cancer-related worry. Physical

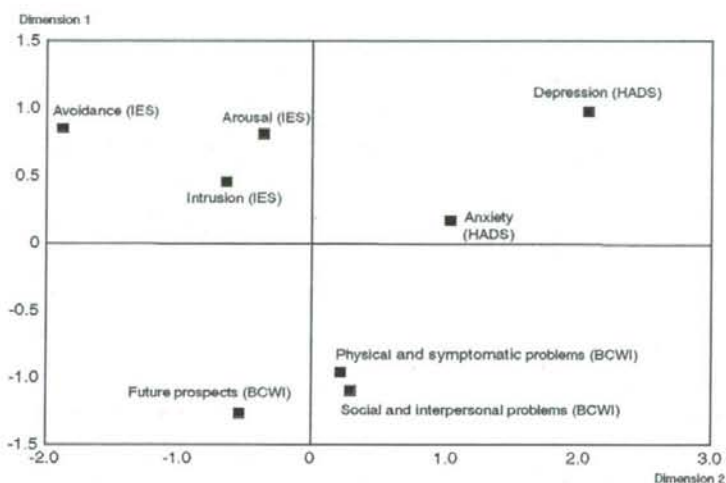
and symptomatic problems covered the domain of actual problems caused by cancer itself: physical symptoms, side effects of treatments, changes of appearance, and sexual issues. For our development data, test-retest reliability was lower than other subscales of BCWI. This indicates that this subscale is sensitive to physical and symptomatic changes of the patients and has content validity. Physical and symptomatic changes were found to be primary concerns of cancer patients in several studies [2–5], and controlling them was a primary purpose of palliative care or supportive care in ordinary medical treatment. Thus, changes of the score in this domain will correspond with the actual outcome of palliative treatments. *Social and interpersonal problems* covered secondary problems caused by cancer, including problems in interpersonal relationships with family members or medical staff, problems on the job, house work, and economic problems. Although these worries will not be influenced directly by cancer itself or cancer treatment, they may be very difficult issues for cancer patients to cope with or solve. Several forms of psychosocial intervention might be effective for these kinds of problems.

**Table 4.** Intercorrelations between Brief Cancer-Related Worry Inventory and other measures

	1	2	3	4	5	6	7	8	9
1. Future prospects (BCWI)	§								
2. Physical and symptomatic problems (BCWI)	0.65***	§							
3. Social and interpersonal problems (BCWI)	0.64***	0.66***	§						
4. Anxiety (HADS)	0.57***	0.48***	0.59***	§					
5. Depression (HADS)	0.27**	0.45***	0.39***	0.58***	§				
6. Intrusion (IES-R)	0.55***	0.56***	0.56***	0.58***	0.40***	§			
7. Avoidance (IES-R)	0.45***	0.40***	0.36***	0.35***	0.19*	0.65***	§		
8. Arousal (IES-R)	0.48***	0.56***	0.54***	0.57***	0.43***	0.77***	0.54***	§	
9. Physical component scales (SF8)	-0.19*	-0.28**	-0.18	-0.23*	-0.40***	-0.27**	-0.13	-0.31**	§
10. Mental component scales (SF8)	-0.41***	-0.34***	-0.42***	-0.55***	-0.42***	-0.58***	-0.32**	-0.60***	0.19*

\* $P < 0.05$ , \*\* $P < 0.01$ , \*\*\* $P < 0.001$ .

BCWI, Brief Cancer-related Worry Inventory; HADS, Hospital Anxiety and Depression Scale; IES-R, Impact of Event Scale Revised; SF8, Medical Outcomes Study Short Form-8.

**Figure 2.** The structure of similarities among subscales of BCWI, HADS, and IES. Kruskal's stress value (= 0.14) and proportion of variance of data (= 0.89). BCWI, Brief Cancer-Related Worry Inventory; HADS, Hospital Anxiety and Depression Scale; IES-R, Impact of Event Scale Revised; SF8, Medical Outcomes Study Short Form-8

The finding that the BCWI was moderately correlated with HADS, IES-R, and SF-8 indicates that the scale has convergent validity. However, when we investigated the detailed differences and similarities among the scales by multidimensional scaling, we found that the distance between the subscales of BCWI and HADS-anxiety was similar to that between BCWI and HADS-depression and their directions were opposite (Figure 2). In addition to, the BCWI subscales were graphically different from the intrusion, avoidance, and arousal subscales of IES-R. If the distance between depression and anxiety in HADS is enough to discriminate two different emotional conditions, the subscales of BCWI were discriminable from HADS-anxiety and all the subscales of IES-R. Therefore, cancer-related worry that the BCWI measures is an interrelated but different and

emotional construct discriminable from anxiety, depression, and PTSD symptoms.

Among discriminable aspects of the BCWI, the difference between worry and anxiety shows that patients with high cancer-related worry are not necessarily in a severely anxious status. In addition, the BCWI can evaluate the contents of each worry and their individual magnitudes, whereas the HADS-anxiety subscale can only measure the intensity of anxious states. This means that measurement of cancer-related worry by BCWI is valuable to clinical practice. For example, assessment of the type of cancer-related worry will contribute to formulation of a psychological intervention for the cancer patient, especially interventions using the problem-solving technique [30,31], because in the earlier stage of the problem-solving technique, making problem-lists is needed



for identifying the problem and setting a priority for solution. The BCWI will be helpful for patients to create their problem-list in a very structured and effective way.

The limitations to this study include the small and limited sample. We developed the items using a breast cancer sample ( $N=112$ ) and confirmed internal consistency and test-retest reliability using a lung cancer sample ( $N=20$ ). These samples are different from samples used in the development phase of this scale. As we used only two different cancer samples, this may limit validity for using the BCWI for patients with other kinds of cancer. However, we suppose that because the items of this scale were developed by reference to a broad range of the articles concerning unmet need, concerns, and stressors of cancer patients, the items in the scale are sufficiently general for application to other cancers.

In conclusion, our study succeeded in developing and confirming the validity and reliability of a scale for assessment of cancer-related worry, the so-called BCWI. The BCWI has only 15 items that enable a brief evaluation of the content and the magnitude of cancer-related worry of cancer patients. The study also confirmed that aspects of cancer-related worry are discriminable from anxiety, depression, and PTSD symptoms. However, to reach a final conclusion about differences in complicated emotions and usefulness for clinical practice in cancer care, further empirical work using the prospective design and academic discussion will be needed.

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