


The Benefit of Enhanced Daycare of Traditional Chinese Medicine for Cancer Treatment Related Adverse Events: A Retrospective Study of Medical Records

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Abstract

Objective: Cancer patients undergo therapies that might lead to severe adverse events. The enhanced daycare of Traditional Chinese medicine (TCM) we describe was intended to help cancer patients suffering from severe adverse events to obtain relief. We used the Taiwan brief version of the Common Terminology Criteria for Adverse Events Version 4.0 (Taiwan brief version questionnaire of CTCAE) as a primary measurement to evaluate the efficacy of the enhanced day care of TCM. The secondary measurements were the Taiwanese version of the Brief Fatigue Inventory (BFI-T) questionnaire and the World Health Organization Quality of Life-BREF (WHOQOL-BREF) questionnaire, which were used to quantify fatigue and quality of life (QOL), respectively. **Methods/Design:** This is a retrospective study of medical records. There were 401 patients treated with enhanced daycare of TCM from June 2017 to November 2019. **Results:** Among 22 common adverse symptoms in the Taiwan brief version questionnaire of CTCAE4.0, 14 symptoms achieved a significant improvement, and the change of the total scores was also statistically significant ($P < .001$). Cancer stages II to IV showed significant improvement on the CTCAE and BFI-T; stage I only showed improvement on the BFI-T. On the WHOQOL questionnaire, there was a statistically significant difference in self-evaluation of the quality of life ($P = .001$) and self-evaluation of the total health condition aspect ($P < .001$). **Conclusions:** The enhanced TCM daycare program helped cancer patients decrease the severity of their adverse events and improve their fatigue and QOL. ClinicalTrials.gov identifier: NCT04606121.

Keywords

enhanced daycare, TCM, adverse events, complementary medicine

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Background

Cancer is a leading cause of death worldwide. Cancer patients undergo different types of treatment, such as surgery, chemotherapy, radiation therapy, targeted therapy, and immunotherapy, based on the stage or type of cancer. However, severe adverse events often occur in response to treatment. A case report review showed that cancer patients can use Chinese herbal medicine as crucial complementary and alternative medicine (CAM) in some Asian contexts.¹ To help cancer patients relieve the symptoms of their treatment, we created an enhanced TCM daycare program as a form of comprehensive therapy²; the program included the use of TCM methods such as acupuncture,^{3–5} Chinese herbal

medicine,^{6,7} massage,⁸ Tai Chi Chuan exercise,⁹ psychological counseling, rehabilitation training, and health promotion education.

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Materials and Methods

Design and Participants

This study was designed as a retrospective medical record study. Medical records from June 2017 to November 2019 were collected from the clinics where the enhanced traditional Chinese medicine daycare program for cancer patients was implemented. This study was approved by the Institutional Review Board of Taipei City Hospital. The study was approved on June 11th, 2020. The ID number is TCHIRB-10905008-E.

The ethical board waived informed consent because of the retrospective nature of the study.

The cancer patients considered for this enhanced traditional Chinese medicine daycare program underwent standard cancer therapy, such as surgery, chemotherapy, radiation therapy, targeted therapy, and immunotherapy. Then, they came to the clinics to be evaluated for inclusion in the program. Using the Common Terminology Criteria for Adverse Events Version 4.0 of the National Cancer Institute (CTCAE),¹⁰ we extracted 22 cancer treatment symptoms that are common in Taiwan to create a questionnaire, that is, the Taiwanese brief CTCAE4.0 questionnaire, to evaluate the cancer patients' symptoms in the selected clinics.

Qualifications of the Participants in the Enhanced TCM Daycare Program

The cancer patients were required to experience at least 2 of the 22 common symptoms with a severity of greater than or equal to grade 2 to participate in the program and receive the enhanced traditional Chinese medicine daycare. If the patients' severity according to the Taiwanese brief CTCAE4.0 questionnaire decreased below 2 symptoms with grade 2 severity among the 22 common symptoms, we considered them to have met the criteria for the completion of the program; if the patients did not participate in the enhanced TCM daycare program for more than 3 days, we withdrew them from the program even if they did not meet the criteria for the completion of the program. We used the clinics' medical records to conduct this study.

The cost of the enhanced TCM daycare program was covered by the National Health Insurance of Taiwan, and the patients only needed to pay 50 Taiwan dollars (1.8 US dollars) out of pocket.

Inclusion Criteria

The medical records from June 2017 to December 2019 of the patients meeting the following criteria were included: (1) age > 20 years old; (2) diagnosis corresponding to

ICD10 codes C00.0-C97; and (3) completion of the Taiwanese brief CTCAE4.0 questionnaire,¹⁰ the Taiwanese version of the Brief Fatigue Inventory (BFI-T)¹¹ and the World Health Organization Quality of Life-BREF (WHOQOL-BREF).^{12,13}

Exclusion Criteria

The subjects were excluded if they did not complete the following questionnaires at pretest and posttest or if they did not complete them correctly: (1) Taiwanese brief CTCAE 4.0 questionnaire, (2) the BFI-T questionnaire, and (3) the WHOQOL-BREF questionnaire.

Enhanced TCM Daycare Program in the Clinics

We offered the enhanced TCM daycare program to cancer patients in the clinics. The process of enhanced TCM daycare is listed in the supplement. (Supplement 1) The cancer patients had to stay at the clinic for at least 6 hours. The program started with Tai Chi Quan as physical exercise. Then, we administered acupuncture and massage therapy twice within the 6-hour period, and based on patients' physical condition, we offered them an additional applicable TCM treatment package. We also offered them oral herbal medicine (Kuan-Sin-Yin), which was constituted with several immunomodulating and anticancer herbs,^{14,15} if they needed it. We offered the patients health promotion courses that were designed by our team, a Chinese medicine team and a Western medicine team; the team members included 1 psychiatrist, 1 psychological counselor, nurses, 1 nutritionist, functional therapists and physical therapists, pharmacists, 1 rehabilitation physician, social workers, and 5 traditional Chinese medicine doctors. The team selected appropriate courses with different health promotion themes for the cancer patients. The psychiatrist provided a training series on yoga,^{16,17} mindfulness-based stress reduction (MBSR)¹⁸⁻²¹ and health education. The psychological counselor provided a training series on meditation²¹ and education on stress management techniques (progressive muscle relaxation, body scanning, stretching exercises and breathing exercises). The nurses provided a training series on self-care practices. The nutritionist provided nutritional education and consultation.^{22,23} The pharmacists provided consultation and education about the interactions of Chinese medicine and Western medicine. The rehabilitation physician, functional therapists and physical therapists provided education about physical exercise.²⁴ The social worker invited cancer survivors (cancer patients who completed their cancer therapy and did not have recurrence for more than 5 years) to share their experiences and attitudes. All patients in the program were required to attend all courses (Supplement 2).

Acupuncture and Massage

Every cancer patient in the program had to have acupuncture twice daily, once in the morning and then again in the afternoon. The TCM doctors devised an individual treatment plan for each cancer patient according to their complaints and physical conditions, so the acupuncture points used were variable but suitable for each cancer patient. The needles were stimulated to achieve the de qi sensation for 30 minutes.

Massage manipulation was performed by the TCM doctors on pain sites if the cancer patients needed it. The doctors used basic techniques of Chinese massage, such as pressing, nipping, finger-pushing, rolling, pushing and wiping, cupping therapy and joint manipulation.

Acupuncture-Related Adverse Events Monitoring

We recorded 3 common adverse events related to acupuncture. The first was subcutaneous bruises, the second was acupuncture fainting, and the third was local infection.

Operation of the Enhanced Daycare Program

The cancer patients were referred to the consultation center from their general clinics. Then, the pretest with the Taiwanese brief CTCAE4.0 questionnaire, the BFI-T and the WHOQOL-BREF was administered to the cancer patients by the 5 traditional Chinese medicine doctors. If the cancer patients met the cutoff score for side effects on the Taiwanese brief CTCAE4.0 questionnaire, they were assigned to the enhanced daycare program and started participating within 3 days. The cancer patients could choose their treatment frequency according to their needs but could not stop participating for more than 3 days. We recommended that the patients be treated every day. If they could not do so, they had to be treated at least once every 3 days; otherwise, they would not be eligible for the program. The Taiwanese brief CTCAE4.0 questionnaire was administered to the patients 1 week after the first treatment day. If the patient still met the criteria for the program, he or she continued in the program and completed the Taiwanese brief CTCAE4.0 questionnaire again 3 days later; this process was repeated until the patient met the criteria for ending the program. Once the program was completed, the 3 questionnaires were administered as a posttest. Posttests were also performed if cancer patients informed the clinic in advance that they would stop the daycare program for more than 3 days in order to go back to cancer therapies. There was only 1 pretest and 1 posttest for each participant. The length of the program varied for each participant. The mean duration of the treatment period was 23.54 ± 18.65 days.

Outcome Measurements

The primary outcome was the Taiwanese brief CTCAE4.0 questionnaire score.¹⁰ There were 22 common adverse events in this questionnaire. Each adverse event had its own severity score from 0 to 5 points, with high scores indicating severe symptoms. We used each subgroup score and the total scores before and after treatment to compare the benefits of the enhanced traditional Chinese medicine daycare program.

Other Measurements

We also used the total scores of the BFI-T¹¹ to quantify the patients' fatigue. The BFI-T is a 10-question questionnaire; the first question is a yes or no question to determine whether fatigue was experienced in the last week. The second to the tenth questions are questions on the degree of fatigue rated from 0 to 10 points, where 0 means no fatigue, and 10 means extreme fatigue. The WHOQOL-BREF^{12,13} was used to determine the cancer patients' quality of life. There are 6 different aspects of the WHOQOL-BREF questionnaire: self-evaluated quality of life, self-evaluated total health condition, physical aspect, mental aspect, social aspect, and environmental aspect. The WHOQOL-BREF questionnaire uses a 5-point Likert scale, where 1 means not good and 5 means good.

Sample Size

We collected medical records from June 2017 to November 2019. There were a total of 401 medical records that satisfied the inclusion and exclusion criteria of the study.

Statistical Analysis

The statistical software we used to manage the data was IBM SPSS version 21. We used paired T tests to compare the pretest and posttest scores of the 3 questionnaires. We also used p-ANOVA to compare the questionnaires across different stages of cancer.

Results

Demographic Data

The enhanced TCM daycare program for cancer patients was started in June 2017; we collected medical records from this date until December 2019. We collected 506 medical records of patients that met the inclusion criteria, and then we excluded 105 medical records of patients that met the exclusion criteria for the reasons listed in the flow chart (Figure 1).

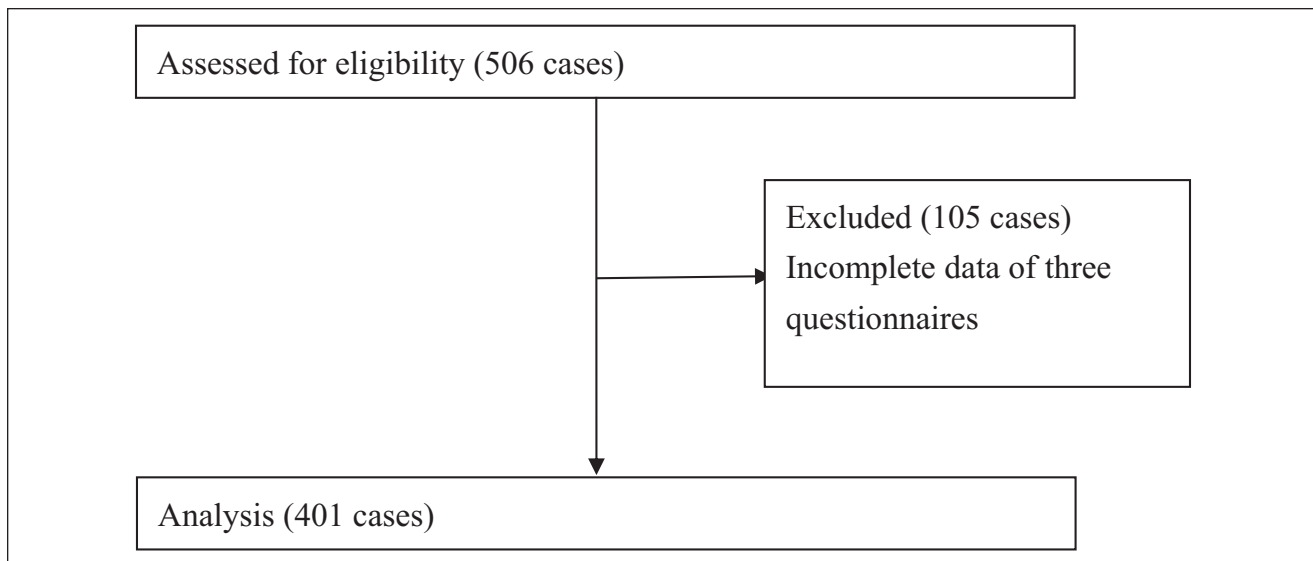


Figure 1. The flow chart of the study.

Table 1. Characteristics of the Participants.

Demographics	n (%)	Mean \pm SD
Sex		
Male	112(27.9)	
Female	289(72.1)	
Age		59.13 \pm 9.24
Height (cm)		159.98 \pm 7.53
Weight (kg)		58.82 \pm 11.13
Cancer stage		
Stage I	23(5.7)	
Stage II	68(17.0)	
Stage III	143(35.7)	
Stage IV	167(41.6)	
Medical utilization		
Clinic attendance per patient (visits)		12.01 \pm 9.95
Duration of treatment period(days)		23.54 \pm 18.65

Abbreviations: Kg, kilogram; cm, centimeter.

The patients' basic information, such as sex, age, height, weight, and the stage of cancer, is listed in Table 1. The distribution of cancer types is shown in Table 2.

Taiwanese Brief CTCAE4.0 Questionnaire

The total scores on this questionnaire decreased from pre- to posttest, which means that the patients' symptoms improved. The pretest score was 13.05 ± 4.78 , and the posttest score was 11.38 ± 4.70 ($P < .001$). There were also 15 symptoms that showed a significant improvement ($P < .05$, Table 3).

BFI-T and WHOQOL-BREF

We used the total BFI-T score to evaluate the patients' degree of fatigue. There was a significant improvement in fatigue in response to the treatment ($P < .001$).

On the WHOQOL-BREF, the first question is a self-evaluation of quality of life, scored as the BREF-A. The second question is a self-evaluation of the total health condition, scored as the BREF-B. The 3rd to 28th questions are divided into 4 sequential aspects: physical aspect (BREF-P), mental aspect (BREF-M), social aspect (BREF-S), and environmental aspect (BREF-E). There were significant improvements in the BREF-A ($P = .001$) and BREF-B ($P < .001$) scores but no significant improvements in the other 4 aspects, as shown in Table 4.

Cancer Stage

Among the 401 patients, 23 (5.74%) had stage I cancer, 68 (16.96%) had stage II cancer, 143 (35.66%) had stage III cancer and 167 (41.65%) had stage IV cancer. The patients with stages II to IV cancer showed significant improvement in their CTCAE and BFI-T scores, but the patients with stage I cancer only improved on the BFI-T. There were no significant differences among the patients with different stages, which means that the enhanced TCM daycare program provided benefits for patients with all stages of cancer. On the WHOQOL-BREF, the patients with stage III and stage IV had significant changes in their BREF-A scores (stage III, $P = .01$; stage IV, $P = .04$), and the patients with stage II and stage III cancer had significant changes in their BREF-B scores (stage II, $P = .002$; stage III $P = .03$). These results are shown in Table 5.

Table 2. Distribution of Cancer Types.

Group	Intestinal cancer	Lung cancer	Breast cancer	Other type of cancer
	n (%)	n (%)	n (%)	n (%)
Female	34 (8.48)	47 (11.72)	134 (33.42)	75 (18.70)
Male	30 (7.48)	23 (5.74)	0 (0.00)	58 (14.46)
Total number	64 (15.96)	70 (17.46)	134 (33.42)	133 (33.17)

Note. The denominator is the total number of medical records (n=401).

Table 3. Differences on the CTCAE.

Group	Pretest (n=401)	Posttest (n=401)	P-value
	Mean ± SD	Mean ± SD	
Total score of CTCAE	13.05 ± 4.78	11.38 ± 4.70	<.001**
Fatigue	1.56 ± 0.59	1.35 ± 0.57	<.001**
Anemia	0.49 ± 0.73	0.47 ± 0.71	.48
Febrile neutropenia	0.07 ± 0.37	0.04 ± 0.24	.08
Pain	1.28 ± 0.78	1.17 ± 0.72	.003**
Diarrhea	0.39 ± 0.74	0.24 ± 0.53	<.001**
Constipation	0.29 ± 0.58	0.25 ± 0.53	.06
Vomiting	0.17 ± 0.52	0.08 ± 0.33	<.001**
Anorexia	0.92 ± 0.89	0.73 ± 0.84	<.001**
Oral mucositis	0.35 ± 0.66	0.29 ± 0.55	.04*
Salivary duct inflammation	0.41 ± 0.65	0.33 ± 0.54	.003**
Dysphagia	0.36 ± 0.64	0.29 ± 0.58	.004**
Dyspnea	0.54 ± 0.75	0.48 ± 0.72	.03*
Cystitis noninfective	0.10 ± 0.35	0.08 ± 0.34	.29
Abdominal distension	0.83 ± 0.70	0.76 ± 0.67	.04*
Dry mouth	0.79 ± 0.60	0.73 ± 0.58	.03*
Anxiety	0.94 ± 0.71	0.81 ± 0.69	<.001**
Depression	0.82 ± 0.68	0.75 ± 0.68	.01*
Insomnia	1.27 ± 0.85	1.12 ± 0.82	<.001**
Cough	0.39 ± 0.61	0.38 ± 0.59	.85
Rash	0.30 ± 0.60	0.30 ± 0.60	1
Palmar plantar erythrodysesthesia syndrome	0.23 ± 0.50	0.24 ± 0.49	.77
Peripheral sensory neuropathy	0.54 ± 0.71	0.47 ± 0.67	.02*

Note. *P<.05 with statistical significance.

**P<.005 with statistical significance.

The only acupuncture-related adverse event recorded in the enhanced TCM daycare program was minor bruising. There was no fainting or local infection due to acupuncture.

Discussion

Enhanced TCM daycare treatment is a comprehensive therapy used for cancer patients who are suffering from the adverse effects of cancer therapies. In our study, the enhanced TCM daycare program was beneficial for more symptoms than the treatments mentioned in a previous systematic review.³ When acupuncture is the main treatment method in an enhanced TCM daycare program, the most commonly used acupoints are Zusanli (ST36), Quchi (LI11), Qihai (CV6), Guanyuan (CV4), Neiguan (PC6),

Table 4. Differences on BFI-T and WHOQOL-BREF.

Group	Pretest (n=401)	Posttest (n=401)	P-value
	Mean ± SD	Mean ± SD	
BFI-T	49.91 ± 18.18	45.66 ± 18.64	<.001**
BREF-A	2.69 ± 0.80	2.79 ± 0.77	.001*
BREF-B	2.22 ± 0.72	2.35 ± 0.73	<.001**
BREF-P	18.84 ± 2.84	18.99 ± 3.04	.22
BRED-M	16.68 ± 2.88	16.80 ± 2.72	.24
BREF-S	12.58 ± 2.14	12.60 ± 2.19	.73
BREF-E	28.49 ± 4.45	29.70 ± 4.44	.17

Note. A: self-evaluation quality of life; B: self-evaluation total health condition.

Abbreviations: P, physical aspect; M, mental aspect; S, social aspect; E, environmental aspect.

*P<.05 with statistical significance.

**P<.005 with statistical significance.

Table 5. Differences on Different Cancer Stages Comparisons.

Group	Cancer stage I	Cancer stage II	Cancer stage III	Cancer stage IV	P-ANOVA
	n=23, 5.74%	n=68, 16.96%	n=143, 35.66%	n=167, 41.65%	
	Mean (SD), P	Mean (SD), P	Mean (SD), P	Mean (SD), P	
CTCAE	-1.96 (2.85), .003**	-1.90 (6.08), .01*	-1.24 (3.84), <.001**	-1.90 (3.80), <.001**	.52
BFI-T	-0.65 (12.44), .80	-4.06 (13.69), .02*	-4.31 (15.4), .001**	-4.77 (14.28), <.001**	.65
BREF-A	0.09 (0.60), .49	0.06 (0.77), .53	0.13 (0.59), .01*	0.10 (0.58), .04*	.91
BREF-B	0.22 (0.60), .10	0.25 (0.63), .002**	0.10 (0.55), .03*	0.10 (0.69), .07	.28
BREF-P	0.00 (1.68), 1	-0.13 (1.96), .58	0.32 (2.27), .10	0.14 (2.68), .51	.63
BREF-M	0.04 (2.01), .92	0.43 (1.83), .06	0.13 (2.03), .43	0.01 (2.31), .97	.59
BREF-S	0.30 (0.97), .15	0.00 (1.11), 1	0.08 (1.18), .40	-0.05 (1.80), .70	.66
BREF-E	0.39 (2.59), .48	0.12 (2.52), .70	0.28 (2.10), .11	0.16 (3.93), .60	.97

Note. P, PAIR-T.

*P < .05 with statistical significance.

**P < .005 with statistical significance.

Taichong (LR3), BaiHui (GV20), and YinTang (EM2). The main theory is to strengthen the body and to eliminate evils, and the second is to balance yin and yang. In addition to the TCM treatment methods, we used health promotion courses and psychological counseling to give the cancer patients comprehensive care to help relieve their symptoms of cancer therapy.

For cancer patients, doing Tai Chi Quan and engaging in physical exercise might increase muscular strength, flexibility and quality of life.⁹ Nutrition education and education by pharmacists can help cancer patients choose healthy food for themselves and avoid drug abuse. Training courses by psychiatrists and psychological counselors might help cancer patients reduce their depression, anxiety and insomnia.¹⁶

The enhanced TCM daycare program was beneficial for patients with all stages of cancer in terms of the CTCAE scores. Regarding the BFI-T scores, there was no benefit for the patients with stage I cancer, but there were benefits for the patients with stages II–IV cancer, possibly because different approaches to cancer therapy are applied to patients with different stages of cancer. The same situation was observed for the WHOQOL-BREF scores, with positive benefits for the patients with stages III–IV cancer in terms of the BREF-A (self-evaluation QOL) scores. We believe this finding might relate to the severity of disease, as late-stage cancers are more harmful than early-stage cancers. Treatments for late-stage cancers are usually harder than those for early-stage cancers.

There were also good effects for the patients with stages II–III cancer on the BREF-B (self-evaluation total health condition) scores, which we think might be related to different treatment strategies for different stages of cancers. Stage I cancer patients may not need chemotherapy, and only targeted therapy or radiation therapy may be performed. A

small portion of stage IV cancer patients' treatment might be palliative, but most of them undergo a very difficult chemotherapy regimen that has severe side effects. TCM treatment may not relieve symptoms quickly enough and effectively enough in the cases of the more serious adverse events experienced by stage IV patients undergoing very difficult chemotherapy regimens, even though significant improvements in side effects, self-evaluated quality of life and fatigue were observed in this study. Although Stage IV patients showed significant improvement in side effects, quality of life and fatigue, these effects did not translate into a perception of overall better health, perhaps due to lack of tumor shrinkage attributable to the program. Seeking more diverse and effective TCM treatment to add to the program should be considered to help increase efficacy of patients with stage IV cancer. Further analysis by cancer type is needed to fully explain these findings.

To the best of our knowledge, this was the first comprehensive TCM daycare program model applied to cancer patients that was demonstrated to effectively relieve their chemotherapy-related adverse effects.

Limitations

There are also some limitations of this study. Since this study was a retrospective medical records analysis, there was no control group. We could only compare the pretest with the posttest results. Each medical record represents a different patient with a different cancer diagnosis, such as breast cancer, lung cancer, intestinal cancer, or liver cancer. There are different treatment regimens for different cancers. Different cancer treatments have different side effects. We could not determine the benefits of the enhanced TCM daycare program for the side effects of specific cancer treatments due to data limitations. In addition, the number of therapeutic visits

during each patient's course of the enhanced TCM daycare program was not the same. Different numbers of treatments might have the treatment effect.

Conclusion

The benefit of the enhanced TCM daycare program was shown based on the CTCAE, BFI-T, and WHOQOL scores. There were significant improvements in the total CTCAE scores and the scores for 15 symptoms, and significant differences in fatigue, self-evaluated total health condition and self-evaluated QOL between pretest and posttest.

The side effects of the enhanced TCM daycare program were very minor. Health promotion education for cancer patients might help them take better care of themselves. We suggest that TCM treatment methods together with a health promotion course (enhanced TCM daycare program) may be a nontoxic, harmless alternative therapy to relieve adverse events in patients undergoing cancer therapies.

Abbreviations and Terminology

1. Traditional Chinese medicine (TCM)
2. Taiwanese brief Common Terminology Criteria for Adverse Events Version 4.0 questionnaire (Taiwanese brief CTCAE4.0 questionnaire)
3. Taiwanese version of the Brief Fatigue Inventory (BFI-T)
4. World Health Organization Quality of Life-BREF (WHOQOL-BREF)
5. Quality of life (QOL)
6. Complementary and alternative medicine (CAM)

Declaration of Conflicting Interests

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Supplemental Material

Supplemental material for this article is available online.

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