<Original Article>

Development of a Nursing Intervention Program to Promote Psychological Adjustment in Adult Women Diagnosed with Metastatic Breast Cancer

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Key words: metastatic breast cancer, nursing intervention program, psychological adjustment, cancer pharmacotherapy

ABSTRACT

The purpose of this study was to develop a nursing intervention program to promote psychological adjustment in adult women diagnosed with metastatic breast cancer (MBC) and to evaluate the validity and clinical applicability of the program. The program was developed based on a review of studies of nursing interventions for these patients and an empirical study of adult women diagnosed with MBC and undergoing cancer pharmacotherapy. The survey was requested from 75 the Certified Nurse in Breast Cancer Nursing (BCN), and 44 of them (58.6 % response rate) consented to participate in the study. The method was a web-based survey that asked about the validity and clinical applicability of the program. Descriptive statistics were used for analysis. More than 90 % of the participants indicated that the program was appropriate. Regarding the clinical applicability of the program, 59.1 % of participants responded "yes" and 34.1 % of participants responded "yes, somewhat". Participants provided comments that would be useful in practice and as educational material for nurses. Some comments indicated the need for collaboration with Certified Nurse in Cancer. The results suggest that the program can be considered as valid and clinically applicable from the point of view of Certified Nurse in BCN. Future intervention studies should apply it clinically and test its effectiveness and usability.

INTRODUCTION

Breast cancer is more likely to metastasize within 2 years of diagnosis [1], and metastatic or recurrent breast cancer is difficult to cure completely. Therefore, the treatment of metastatic breast cancer (MBC) focuses on cancer pharmacotherapy to prolong life and relieve symptoms, which is mainly initiated on an outpatient department. The

prognosis of MBC varies by subtype, with median overall survival ranging from 14.2 to 58 months [2]. When adult women with MBC are diagnosed by their physicians, they are faced with the threat of death and the conflict of painful anticancer pharmacotherapy, they consolidate their resolve to save their lives and begin cancer pharmacotherapy [3]. Patients with MBC undergoing cancer pharmacotherapy experience increased disruption of their lives due to mul-

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tiple symptoms, a wavering of their confidence in continuous chemotherapy [4], and decreased quality of life (QoL) [5]. Patients with MBC can achieve psychological adjustment with the support of family members and healthcare professionals, among others [3]. However, patients do not receive medical care from outpatient nurses immediately after being diagnosed with MBC, and they have a sense of dissatisfaction [6, 7]. The information and support provided to patients with MBC is inadequate compared to the support provided for early breast cancer diagnosis [6]. In addition, outpatient nurses perceive that their involvement with patients with MBC is insufficient [7, 8]. In other words, nurses are expected to alleviate the psychological distress of adult women diagnosed with MBC and provide support aimed at improving their QoL while undergoing cancer pharmacotherapy, but the support they provide is far from sufficient.

Previous studies in patients with MBC have shown that psychosocial support is effective in significantly reducing anxiety, depression, and stress and improving QoL [9–11], physical symptoms, and self-efficacy in patients with MBC [12]. However, no systematic and continuous nursing intervention program has focused on the psychological adjustment of adult women diagnosed with MBC and undergoing cancer pharmacotherapy.

Therefore, this study aims to develop a nursing intervention program for patients diagnosed with MBC and to examine the validity and clinical applicability of its content and methods from Certified Nurse in Breast Cancer Nursing (BCN). The development of such a nursing intervention program would enable nurses to provide systematic and continuous interventions for patients diagnosed with MBC, which would alleviate their psychological distress, improve their QoL, and likely lead to reduced dissatisfaction. In addition, it is believed that the development of a nursing intervention program will become the standard for outpatient nursing care of patients diagnosed with MBC and will contribute to improving the quality of cancer nursing practice.

RESEARCH METHODS

Definition of Terms

In this study, psychological adjustment is defined as "the state of psychological stability in which anxiety, depression, and negative emotions, which are stress reactions caused by the initial diagnosis of MBC and the need to undergo cancer pharmacotherapy, are reduced and the patient is able to face to breast cancer".

Development of a Nursing Intervention Program

Purpose of Developing a Nursing Intervention Program

The purpose of developing the nursing intervention program was to enable Certified Nurse in BCN to promote psychological adjustment and improve QoL for adult women diagnosed with MBC and undergoing cancer pharmacotherapy. This program was positioned as an effort to promote psychological adjustment in adult women diagnosed with MBC (**Figure 1**).

Design of the draft nursing intervention program (Table 1)

This nursing intervention program was created based on the results of a literature review on the QoL of patients with MBC undergoing cancer pharmacotherapy [13], the qualitative empirical research on the process of reaching psychological adjustment of adult women in this group [3], the results of a systematic review of psychological interventions for patients with MBC [14–16], and the supportive care framework [17].

The overall goals of the program were to reduce the anxiety and depression of adult women diagnosed with MBC and undergoing cancer pharmacotherapy, to reduce their conflict and resistance to cancer pharmacotherapy, and to improve their QoL by adjusting their lives to the psychological changes caused by cancer pharmacotherapy and its side effects.

The components and interventions methods of this program have been divided into two phases: the diagnostic phase and the treatment phase. Phase 1 begins with the diagnosis of MBC and ends with the decision for cancer pharmacotherapy, and Phase 2 begins with the initiation of cancer pharmacotherapy and ends when the treatment is on track. The components of phase 1 were helping patients express their feelings about MBC and cancer pharmacotherapy, making autonomous decisions about cancer pharmacotherapy, becoming aware of and using the support of those around them, and preparing for life to cope with future treatment. The components of phase 2 were helping patients understand how to manage side effects, adjusting their lives to cancer pharmacotherapy and its side effects, effectively utilizing the support of those around them, and effectively coping with negative emotions caused by the disease and treatment.

The intervention subjects were female breast cancer patients between the ages of 20 and 65 who were diagnosed with distant metastases during or after treatment for early breast cancer. Exclusion criteria were patients with a history of psychiatric disorders requiring special intervention and patients in the terminal stage of the disease who had stopped active treatment.

The intervention method was face-to-face individual intervention; five sessions of 30 minutes each. The intervention providers were Certified Nurse in BCN who decided to implement this program on an outpatient department. Then, because of Certified Nurse in BCN need to understand and clinically apply the proposed draft of the nursing intervention program, a nursing practice guide was developed by the researchers.

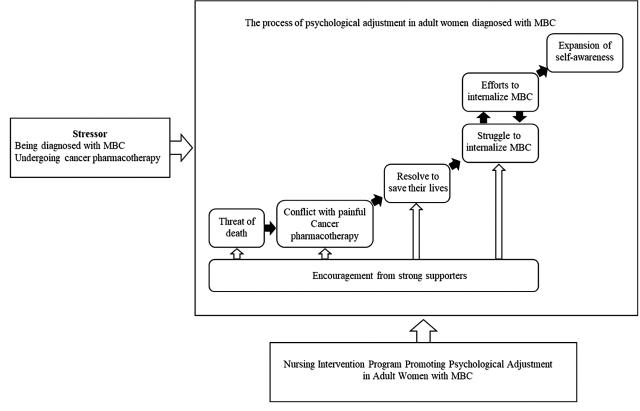


Figure 1 Positioning of the Nursing Intervention Program

Evaluation of the draft nursing intervention program *Participants*

75 out of 325 Certified Nurse in BCN whose names and affiliations were reported to the Japanese Nursing Association as of December 2022 were randomly selected as participants.

Survey period

The study period was from November to December 2022.

Data Collection Method

Participants received an informed consent document and informed consent form by mail. Data were collected via a web-based survey. The survey form was sent and received via SSL-encrypted communication, and the data were encrypted for protection. A survey included items that asked about the participant characteristics, the validity of the design of the nursing intervention program (16 items), and the clinical applicability (3 items). The validity section asked for responses on the extent to which the draft nursing intervention program reflects Certified Nurse in BCN practice. The clinical applicability section asked the Certified Nurse in BCN how effectively the program can be used in clinical nursing practice and in providing educational support to outpatient nurses. Response options were rated on a 4-point scale from "appropriate" to "not at all appropriate". Respondents were asked to describe areas of usefulness or improvement.

Analysis method

The numerical data obtained were analyzed using descriptive statistics. Descriptive data were extracted and summarized for each question item.

Ethical considerations

This study was approved by the ethics committee of Osaka Medical and Pharmaceutical University (approval number 2022-115). Participants were informed in writing of the purpose and methods of the study, that participation was voluntary, and that they could withdraw at any time. Written informed consent was obtained, and efforts were made to ensure anonymity.

RESULTS

Summary of participant characteristics (Table 2)

The survey was completed by 44 individuals (58.6 % response rate). Of the BCNs, 1 was in their 20s, 3 in their 30s, 23 in their 40s, 15 in their 50s, and 2 in their 60s. Their average experience as BCNs was 9.5 ± 3.7 years.

Session 1; Meta	istatic breast cancer at time of diagnosis
Patient goals	 Being able to express negative emotions caused by the diagnosis Understand the purpose of cancer pharmacotherapy
Details and	1. Listen to the patient express her feelings
Method	2. Accept the doctor's explanations and confirm what you understand
	3. Provide information about cancer pharmacotherapy according to the patient's needs.
Session 2; At ti	me of cancer pharmacotherapy decision making
Patient goals	1. Reduce negative feelings about the disease and its treatment
	2. Reduce feelings of conflict and resistance to cancer pharmacotherapy
	3. Be able to prepare for starting cancer pharmacotherapy with the support of those around them
Details and	1. Accept and notice the change in their emotions since the last session
Method	2. Accompany the patient until they can make an informed decision
	3. Explain the possible side effects and how to manage them, and encourage the patient to be prepared
Session 3; 8 day	ys after the starting treatment, or the second cycle of treatment
Patient goals	1. Explain the characteristic side effects of treatment and how to manage them
	2. Be able to adapt life and work to the treatment and its side effects
Details and	1. Evaluate side effects using Common Terminology Criteria for Adverse Events (CTCAE) and suggest
Method	medications to the physician according to symptoms
	2. Identify concerns and adverse effects of side effects and consider solutions that fit the patient's lifestyle
	3. Share information with physicians, pharmacists, and nurses in related departments
Session 4; secon	nd or third cycle of treatment
Patient goals	1. Understand how to effectively manage side effects
	2. Be able to express feelings and hopes about the disease and its treatment
	3. Anticipate the possibility of regaining daily activities
Details and	1. Appreciate the patient's attitude and efforts to find effective ways to cope with side effects
Method	2. Work with the patient to find ways to manage side effects according to the patient's needs
	3. Counsel the patient about their new lifestyle and work issues
	4. Watch over the patient as she deals with the negative emotions caused by the disease and its treatment
Session 5; third	or fourth cycle of treatment
Patient goals	1. Reduce negative feelings about the disease and its treatment and be able to express positive words
0	2. Being able to express commitment to work on things she has given up on
Details and	1. Motivate the patient to look for small goals to achieve and things to hope for in her life
Method	2. Understand what the patient has given up and encourage her to work toward what she has given up
	3. Ask the patient about the positive aspects of her treatment and tell her about the positive changes in he
	life

Table 1 Draft Nursing Intervention Program (excerpts)

Validity of the draft nursing intervention program (Table 3, Table 4)

At least 90 % of study participants reported that the overall goals, components, intervention methods, and timing of the nursing intervention program were either "appropriate" or "somewhat appropriate". All participants reported that the five sessions were "appropriate" in terms of patient goals and intervention content. Positive opinions included "it is easy to use as a reference, since concrete indications of the timing of intervention are provided", "the program also indicates that the intervention should be stopped at times, which reduces the nurse's sense of inadequacy", and "the content of the program makes the patient feel safe and satisfaction". Areas for improvement included "collaboration with Certified Nurse in cancer nursing is needed," and "a description of how to intervene if the patient's anxiety or depression persists is needed". Other opinions included "the content of the support is specific and can also be provided by outpatient or chemotherapy nurses".

Table 2Summary of study participants (n = 44)

Item		n (%)
Age	20s	1 (2.3)
	30s	3 (6.8)
	40s	23 (52.3)
	50s	15 (34.1)
	60s	2 (4.5)
Institution	Hospital	41 (93.2)
	Clinic	3 (6.8)
Department	Outpatient department	21 (47.7)
(multiple answers)	Ward	8 (18.1)
	Chemotherapy center	6 (13.6)
	Nursing department	5 (11.3)
	Others	8 (18.1)

Clinical applicability of the draft nursing intervention program (Table 5, Table 6)

Regarding the program's usefulness in clinical nursing practice activities, 59.1 % responded "yes" and 34.1 % responded "yes, somewhat". Regarding its usefulness in providing educational support for outpatient nurses, 72.7 % responded "yes" and 25 % responded "yes, somewhat". Regarding whether outpatient nurses can perform nursing practice using the nursing intervention program, 36.4 % responded "yes" and 52.3 % responded "yes, somewhat". Positive opinions included "we can be used in practice", "outpatient nurses can provide consistent care with the same goals" and "it can become an educational tool for outpatient nurses". Areas for improvement included "it difficult for outpatient nurses to find time to intervene with patients", and other opinions included "outpatient nurses must be trained to understand and implement the program".

Table 3Validity of the draft nursing intervention program (n = 44)

Evaluate items	appropriate	somewhat appropriate	not so appro- priate	not at all appropriate n (%)	
	n (%)	n (%)	n (%)		
Overall Goals of the Program	41 (93.2)	3 (6.8)	0 (0)	0 (0)	
Components of the Program					
1) From diagnosis to treatment decision making	38 (86.4)	6 (13.6)	0 (0)	0 (0)	
2) From initiation to completion of treatment	37 (84.1)	7 (15.9)	0 (0)	0 (0)	
Intervention methods of the Program					
1) Face-to-face intervention	37 (84.1)	5 (11.4)	1 (2.3)	1 (2.3)	
2) Timing of intervention	33 (75.0)	10 (22.7)	0 (0)	1 (2.3)	
3) Frequency of intervention	25 (56.8)	16 (36.4)	2 (4.5)	1 (2.3)	
In terms of patient goals for each session					
1) First session	37 (84.1)	7 (15.9)	0 (0)	0 (0)	
2) Second session	41 (93.2)	3 (6.8)	0 (0)	0 (0)	
3) Third session	41 (93.2)	3 (6.8)	0 (0)	0 (0)	
4) Fourth session	39 (88.6)	5 (11.4)	0 (0)	0 (0)	
5) Fifth session	33 (75.0)	11 (25.0)	0 (0)	0 (0)	
Intervention content of each session					
1) First session	37 (84.1)	7 (15.9)	0 (0)	0 (0)	
2) Second session	41 (93.2)	3 (6.8)	0 (0)	0 (0)	
3) Third session	38 (86.4)	6 (13.6)	0 (0)	0 (0)	
4) Fourth session	41 (93.2)	3 (6.8)	0 (0)	0 (0)	
5) Fifth session	39 (88.6)	5 (11.4)	0 (0)	0 (0)	

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Table 4 Opinions on the validity of the draft nursing intervention program (n = 44)

	Summary of Opinions
Positive	• The program focuses on the patient's psychological state after being diagnosed (with MBC) and their struggles and QoL during treatment
	 It is easy to use as a reference, since concrete indications of the timing of intervention are provided Selects the areas in which I would like to intervene
	• Detailed descriptions of interventions and methods make the program easy to use even when it is diffi- cult to respond to the patient
	• The program also indicates that the intervention should be stopped at times, which reduces the nurse's sense of inadequacy
	• I am aware of the program during practice and therefore feel that it is compatible with me
	It allows me to be considerate of the patient who is experiencing the pain of endless treatmentThe content of the program makes the patient feel safe and satisfaction
Areas for improvement	• A description of the patient's psychological state would further enhance the nurse's understanding of the patient's condition
-	• Since work was mentioned in the goals, details of employment support should also be provided
	 The intervention times are ideal, but there are too many for the Certified Nurse in BCN to handle alone Collaborative efforts by Certified Nurse in cancer nursing are needed
	• Because anxiety and depression can persist for three months or more, it is difficult to set a goal for the end of nursing intervention
	• A description of how to intervene if the patient's anxiety or depression persists is needed
Others	 Content of support is specific and may be provided by outpatient or chemotherapy center nurses Some content of nursing intervention overlaps with support provided by pharmacists and outpatient chemotherapy center nurses

Table 5 Clinical applicability of the draft nursing intervention program (n = 44)

Evaluate items	Yes	Somewhat yes	Somewhat None	None
	n (%)	n (%)	n (%)	n (%)
Helpful in clinical nursing practice	26 (59.1)	15 (34.1)	3 (6.8)	0 (0)
Helpful in providing educational support to outpatient nurses		11 (25.0)	1 (2.3)	0 (0)
Outpatient nurses can practice caring using the following programs	16 (36.4)	23 (52.3)	4 (9.1)	1 (2.3)

DISCUSSION

Validity of the draft nursing intervention program

The overall goals, components, intervention methods of the program, and each session were generally considered appropriate, indicating that the validity of the draft nursing intervention program was assured from the perspective of Certified Nurse in BCN. The draft program is unique in that it is based on the results of an empirical study of patients with MBC [3] and is divided into two phases: the diagnosis phase and the treatment phase. A study of Japanese cancer patients reported that the first six months after cancer diagnosis are a risk period for suicide, especially the first month [18]. In particular, suicide prevention interventions are more necessary for patients with advanced cancer after diagnosis than for those with early-stage cancer [19]. Therefore, this program was evaluated as appropriate because BCNs intervene from the time of MBC diagnosis. In addition, cancer patients experience heightened anxiety before and after being informed of their cancer, and although this acute anxiety gradually subsides, it resurfaces when treatment begins [20]. Patients with MBC have complex physical symptoms due to the additional physical symptoms associated with metastases and side effects of cancer pharmacotherapy, resulting in decreased QoL [21]. The best time for nursing intervention to be effective is as early as possible when the patient feels they are in a predicament [22]. Therefore, this program was evaluated as appropriate because nursing intervention at the beginning of treatment is responsive to changes in the psychological state of patients with MBC. In

Table 6 Opinions on the clinical applicability of the draft nursing intervention program (n = 44)

	Summary of Opinions
Positive	 Clear goals and intervention methods are broken down into time frames so that we can be used in practice. It is useful in practice because no nursing program intervenes in the psychological adjustment process for patient with MBC It can be practiced while confirming whether perspectives are missing Outpatient nurses can provide consistent care with the same goals The quality of breast cancer care can be improved as nurses who practice unconsciously become more aware of what they are doing It can become an educational tool for outpatient nurses who have indicated that they find it difficult to support patients with MBC Concrete information in the program can be used by inexperienced nurses
Areas for improvement	 Outpatient nurses come from a variety of backgrounds, so there are a few things to consider when using the program Few and busy outpatient nurses, making it difficult for outpatient nurses to find time to intervene with patients
Others	 Outpatient nurses are more likely to use this program if they have a consultant Not limited to Certified Nurse in BCN, but would like to use it in collaboration with outpatient nurses, chemotherapy center nurses, etc Outpatient nurses must be trained to understand and implement the program

addition, the five sessions were similar to aspects of nursing practice for patients diagnosed and treated for recurrent or MBC conducted for Certified Nurse Specialist in Cancer Nursing and Certified Nurse in BCN [23], and the program may have been rated as appropriate because it reflected clinical cancer nursing practice. However, in an empirical study of the process leading to psychological adjustment in adult women diagnosed with MBC and undergoing cancer pharmacotherapy, some adult women did not achieve psychological adjustment [3]. The challenge for this program is to examine how to collaborated with the palliative care team and other professionals to patients with MBC who continue to experience anxiety and depression at the end of the fifth session. In the future, it will be necessary to refine the program based on these issues.

Clinical applicability of the draft nursing intervention program

Participants responded positively to the clinical applicability of the program. The program was developed based not only on the results of a qualitative empirical study of adult women diagnosed with MBC and undergoing cancer pharmacotherapy [3], but also on the results of a systematic review of psychological interventions for patients with MBC [14–16], and was thus examined from all perspectives, making it suitable for clinical practice.

The practice of outpatient nursing has become more sophisticated and extensive, and the challenges of outpatient nursing include nursing staffing, human resource development, and medical treatment support [24]. Moreover, continuing education for nurses faces problems such as nursing staff shortages and difficulties in planning training programs [25], and there is growing recognition of the importance of on-the-job training. In addition to being useful for Certified Nurse in BCN practice, this program "can also be used by outpatient nurses" and "can serve as an educational resource for nurses" because the interventions are divided into diagnostic and treatment phases, patient goals are set for each session, specific nursing interventions are presented, and a nursing practice guide is provided.

Meanwhile, patients with MBC suffer from psychological distress related to cancer or its treatment [26]. As outpatient nurses have different levels of knowledge and experience required in practice for patients with MBC, this seems to be the reason why participants felt that "training for outpatient nurses is necessary". In the future, it may be necessary to develop a systematic training program on breast cancer treatment, nursing, and communication skills for outpatient nurses to increase the number of nurses who can provide interventions. In addition, a review of the outpatient nursing system, including reimbursement, is needed to apply this program clinically. As cancer care has shifted to the outpatient setting, the standard for outpatient nurse staffing is "one nurse for every 30 patients", and the fact that this has not changed since 1948 may be a factor. Sakai et al [27]. point out that nurses' work is complicated by the staffing of outpatient nursing positions and that it is difficult to listen to patients' problems sufficiently in the outpatient setting. On the other hand, the Certified Nurse in BCN is eligible for the Cancer Patient Instruction and Management Fee, which was newly established in the 2014 reimbursement. In the future, it would be necessary to secure outpatient nurses and improve the environment to make this program applicable to clinical practice, including having nurses present when the patient receives a diagnosis of metastatic cancer. If such improvements are implemented, the clinical application of this program may facilitate the process of psychological adjustment in adult women diagnosed with MBC and improve their QoL as they continue cancer pharmacotherapy.

Limitations of the study and issues for the future

This study examined the validity and clinical applicability of the nursing intervention program, which needs to be refined based on the results of the study. A future challenge is to apply this refined program to patients with MBC and verify its efficacy and usability.

CONCLUSION

This study design of the draft nursing intervention program to promote psychological adjustment in adult women diagnosed with MBC and evaluated its validity and clinical applicability from the perspective of Certified Nurse in BCN. Results indicated that the goals, structure, and intervention methods of the program were generally well received and the validity of the program was observed. The program was found to be clinically applicable and participants believed it could be used in practice and as educational material. A future challenge is to apply this program clinically, after making the necessary modifications, and to verify its efficacy and usability through intervention studies.

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DISCLOSURE STATEMENT

The authors declare no conflicts of interest associated with this manuscript.

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