



Effectiveness of a phone-based support program on self-care self-efficacy, psychological distress, and quality of life among women newly diagnosed with breast cancer: A randomized controlled trial

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ABSTRACT

Purpose: This study aimed to determine the effectiveness of a Phone-Based Support Program (PBSP) for newly diagnosed women with breast cancer.

Methods: A two-group repeated measures randomized controlled trial was designed. Participants included 94 patients aged 18–60 years who were newly diagnosed with breast cancer and undergoing chemotherapy in a tertiary hospital in China. They were randomly assigned to the intervention and the control groups. Participants in the intervention group were enrolled in a four-session PBSP, consisting of four interactive sections: learning, discussion, ask-the-expert, and personal stories, plus the routine care. Outcomes included patients' self-care self-efficacy, psychological distress (including symptom distress, anxiety, and depression), and quality of life. These were assessed at three time points: pre-intervention (T1), post-intervention (T2), and follow-up (T3) by using the self-care self-efficacy scale, the M.D. Anderson Symptom Inventory, the hospital anxiety and depression scale, and the global health status scale.

Results: After completion of the intervention, participants in the intervention group had significantly ($p < .001$) higher self-care self-efficacy (T2: $M_{diff} = 11.49$, T3: $M_{diff} = 22.33$), better quality of life (T2: $M_{diff} = 8.18$, T3: $M_{diff} = 17.19$), lower symptom distress (T2: $M_{diff} = -26.68$, T3: $M_{diff} = -54.76$), less anxiety (T2: $M_{diff} = -2.52$, T3: $M_{diff} = -5.11$), and less depression (T2: $M_{diff} = -3.61$, T3: $M_{diff} = -6.71$) than those in the control group.

Conclusion: These findings indicate that the PBSP is effective. Healthcare professionals, especially nurses, could utilize it to enhance self-care self-efficacy and quality of life, as well as decrease psychological distress among women newly diagnosed breast cancer.

Registration: The Thai Clinical Trial Registry #TCTR20230321010.

1. Introduction

In China, the incidence of breast cancer has risen faster than the global average over the past two decades and is expected to reach 805,116 deaths per year by 2030 (Lei et al., 2021). The Global Cancer Observatory (GLOBCAN) reports that breast cancer has the highest incidence among Chinese women with an age-standardized rate (ASR) of 21.6 per 100,000 (Ao et al., 2019; Zhu and Ma, 2021).

Breast cancer is mainly treated with surgery, radiation, chemotherapy, hormonal treatment and other methods (Nader-Marta et al., 2024). Breast cancer after surgery bring unhealthy affects for patients,

such as physical changes, functional changes, axillary web syndrome, lymphedema, and other pain syndromes. Chemotherapy is routinely commenced within six weeks of surgery if indicated (Stewart et al., 2022). Chemotherapy generates several side effects in physiological and psychological disturbance, including pain, insomnia, nausea, loss of appetite, fatigue, and hair loss (Lowe et al., 2022), and depression, anxiety, and worry (Millan, 2022). The damages of these side effects are correlated with the time and duration of chemotherapy, relapse occurrence and stages of cancer, where they have a negative impact on the patients' psychological distress, including symptom distress, anxiety, and depression (Oh and Cho, 2020), as well as quality of life (Chovanec

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et al., 2021). One avenue worth exploring is how to enhance the rehabilitation and improve the quality of life for women who have undergone breast cancer surgery and chemotherapy.

Compared to people who have had breast cancer for longer, newly diagnosed patients often have more difficulty regulating their emotions, maintaining their quality of life, developing self-esteem, and developing effective coping strategies (Yao et al., 2019). These challenges stem from a lack of familiarity with the disease trajectory and treatment processes, leading to heightened feelings of uncertainty and vulnerability. As a result, newly diagnosed patients may experience more profound emotional distress and a steeper decline in their quality of life (Lee et al., 2023).

Self-care involves activities aimed at maintaining health and well-being. Self-efficacy, as defined by Bandura (1977), refers to the belief in one's ability to successfully execute the necessary actions to handle future situations. This concept plays a vital role in self-care, as a person's belief in their own capability of performing self-care activities effectively is crucial for actual engagement in these practices. Self-care self-efficacy (SCSE) applies the self-efficacy concept specifically within the domain of self-care (Lyu et al., 2024). Self-care self-efficacy was a person's confidence to perform behaviors in own caring activities. Psychological distress in breast cancer patients encompasses a wide range of emotional and cognitive difficulties that can occur before, during and after the disease and treatment, usually refers to the anxiety, depression, fear, and stress that patients often experience. These emotional states can be triggered by a variety of factors, such as the shock of diagnosis, the uncertainty and side effects of treatments, along with concerns about body image changes and cancer recurrence, have been shown to impact the women's QOL (Andreu et al., 2022; Hassen et al., 2019; Park et al., 2020). Similarly, associated chemotherapy with a host of physical and emotional issues, including anxiety, pain, nausea/vomiting, body image alterations, increased fatigue, among other side effects, leading to a reduced quality of life (Delikanli et al., 2023). Improving self-care self-efficacy among chronically ill patients correlates with reduced depression levels and enhanced physical function, social support, goal attainment, quality of life, and overall positive health status (Lee and Oh, 2020; Norman et al., 2020; White et al., 2019; Wong et al., 2021). Due to the important role of self-care self-efficacy, targeted interventions that focus on self-care self-efficacy development among postoperative breast cancer patients undergoing chemotherapy are urgently needed.

Chemotherapy-induced symptom distress, including pain, insomnia, and nausea, significantly contributes to the overall psychological burden faced by these patients (Ariza-Garcia et al., 2019). This symptom distress is not merely a physical experience; it intertwines with and exacerbates psychological distress, leading to elevated levels of anxiety and depression (Chen et al., 2024). The prevalence and intensity of these psychological reactions are closely linked to the duration and intensity of chemotherapy, the occurrence of relapses, and the stage of cancer (Oh and Cho, 2020).

Further complicating the issue is the impact of these treatment-related side effects on quality of life, which encompasses both the negative aspects, such as psychological distress (e.g., depression and anxiety), and positive aspects, like life satisfaction and self-esteem (Belzer et al., 2024; Chovanec et al., 2021). The intersection of physical symptom distress with psychological distress creates a complex clinical picture that necessitates a holistic approach in nursing care. Addressing both the physical and psychological needs of breast cancer patients is crucial for improving their overall well-being and quality of life.

Emerging literature suggests the effectiveness of mobile health interventions in areas such as weight management and depression screening among breast cancer patients (Horn et al., 2023; Uemoto et al., 2022). An RCT using an Interactive Digital Education Aid for 133 breast cancer patients to facilitate decision-making, the study group reported higher satisfaction with the method of information delivery (Heller

et al., 2008). In a randomized controlled trial, Yanez et al. (2018) assessed a smartphone application designed to enhance health-related quality of life (HR QoL) and alleviate cancer-specific distress among Hispanic breast cancer survivors in America.

Bandura's model (1997) identifies four key sources influencing self-efficacy: performance accomplishments, vicarious experience, verbal persuasion, and emotional arousal, all of which directly shape self-efficacy (Shi et al., 2023). Therefore, we developed and tested the program 'Phone-Based Support Program' (PBSP) and found that it was feasible (Chen et al., 2024). The purpose of this study was to determine the effectiveness of the PBSP for women newly diagnosed with breast cancer undergoing chemotherapy. The study objectives were to:

1. Compare self-care self-efficacy, quality of life, and psychological distress (including symptom distress, anxiety, and depression) between the intervention and the control participants at post-intervention (T2) and follow-up (T3), and
2. Compare the changes over time across three point times (pre-intervention [T1], post-intervention [T2], and follow-up [T3]) of self-care self-efficacy, quality of life, and psychological distress (including symptom distress, anxiety, and depression) to assess the sustainability of the PBSP's effects within the intervention participants.

These findings would offer both theoretical insights and practical implications for future clinical endeavors. We hypothesized that comparing with receiving only routine care, the PBSP is more effectiveness in enhancing the women's self-care self-efficacy, quality of life, and alleviating psychological distress.

2. Methods

2.1. Study design

A randomized controlled trial (RCT) with single-blinded two-group repeated measures was conducted.

2.2. Participants

We recruited participants from a breast surgery and oncology department of a tertiary hospital in China, from April to July 2023.

The inclusion criteria were: (1) age between 18 and 60 years, (2) non-metastatic, or stage II or lower diagnosed in the past 3–8 weeks, (3) received chemotherapy following their surgical treatment, (4) could reach the Internet via a mobile device, (5) could be contacted via the mobile phone and able to use WeChat, and (6) could communicate with Chinese Mandarin. The exclusion criteria were: (1) had a coexisting major physical problems, such as any physical surgery except for the surgery treatment for breast cancer, conditions or afflictions leading to potential lifelong disability, severe chronic diseases, deep coma, irreversible paralysis, or critical brain injuries, (2) had a chronic mental dysfunction as diagnoses by a psychiatrist, and (3) failed to complete all sessions of the PBSP. The discontinuation criteria were: (1) serious diseases emerged during an implementation session, and (2) self-withdrawal or disappeared from the study.

2.3. Sample size

We employed the G*power software (3.1.9.7) (Faul et al., 2009) to compute power analysis and sample size. A recent feasibility study tested effects of the PBSP on self-care self-efficacy of women with breast cancer (Chen et al., 2024). They reported a large effect size of 0.83. However, evidence suggests that the effect size came out from a small sample of a pilot study may be greatly influenced by chance. It is more appropriate to select a smaller effect size to obtain a more reliable and conservative evaluation. Thus, we used an effect size of 0.35 for the calculation (Kraemer and Blasey, 2015; Lakens, 2022). To attain a

statistical power of 0.80 with a significance threshold set at 0.05, the calculated number of total samples was 72. Subsequently, we added 30% of this number to compensate as an attrition rate from prior study (Grunfeld et al., 2019). A total of 94 women, 47 participants in each group were required for this study.

2.4. Randomization

All participants who met the study criteria and provided written informed consent were enrolled. After pre-intervention assessments, participants were randomly assigned to either the intervention or control group using Excel-generated random numbers. The allocation was concealed using sequentially numbered, sealed, and opaque envelopes. Due to the nature of the intervention, full blinding was not possible. To mitigate this, a single-blind design was employed, with two research assistants (RAs) responsible for enrollment and data collection to ensure impartiality.

2.5. Intervention

2.5.1. The phone-based support program (PBSP) intervention

The principal investigator (PI) created the PBSP guided by the Bandura's self-efficacy theory (1997) and adapted from the Breast Cancer e-Support program (Zhu et al., 2020). The program was executed using the 'WeChat' platform, a service provided by Tencent Corporation, located in Guangzhou, Guangdong Province, China. The PBSP was designed to provide support to women from the start of their first chemotherapy cycle until the commencement of the third cycle, spanning a total of 7 weeks. One RA assisted the intervention group participants in joining the relevant WeChat groups. This arrangement enabled participants to access the PBSP at their convenience, from any time. The results were assessed by another research assistant (RA) at the conclusion of the initial cycle (T2) and during the follow-up (T3) at the onset of the third chemotherapy cycle.

The PBSP was structured into four sessions spanning three weeks, featuring four reciprocal elements: (a) learning, (b) discussion, (c) ask-the-expert, and (d) personal stories groups. These online reciprocal groups operated continuously for a week, incorporating both appointed simultaneous meetings and non-simultaneous text interactions. The PI served as the facilitator for group discussions and provided expert guidance when needed.

The Learning group, formed as part of the PBSP, was directed and coordinated by the lead researcher, tailored to address the specific questions and concerns brought up within the program. In order to protect women's privacy, patients were encouraged to send questions to experts privately in the Ask-Expert Group, and general questions were discussed in the Discussion group. A breast oncologist in the hospital was invited to participate in the PBSP. The physician was on duty every Tuesday to answer patients' questions. The PBSP intervention consists of 4 sessions (week 1–3).

Week 1: Session #1: The aim was to build trusting relationships between the researcher and participants. The research met them one by one on site. Activities in this session include discussing current state of physical and psychological, attitude of life of participants, attitude of life of participants, and strengthening the confidence of participants in privately. Session #2: It was to understand the reality of PBSP. Activities included exploring cognitive about PBSP among participants and encouraging participants to practice PBSP by themselves. Participants saved 10 videos and learned them.

Week 2: Session #3: The aim was to help patients as much as possible and answer questions. The participant may ask questions what they record it during watching videos in the Ask-the-expert group; the participants can discuss all problems in the Discuss group.

Week 3: Session #4: This session aim was to reflect and evaluate the whole process on site one by one. Activities include watching 3 video-recorded encouraging stories, commending participants' intention to

apply PBSP, answering all questions from the beginning until the participants were satisfied and clearly understand, and thanking peer participants. Summary of the PBSP presented in Table 1.

2.5.2. Routine care

Routine care encompasses expert advice from hospital medical staff during the 2 days of hospital stay for each chemotherapy regimen. Prior to commencing treatment, nurses deliver guidance on chemotherapy protocols and potential side effects, and distribute a paper breast cancer health education manual, which includes diet, functional exercise of the affected limb, follow-up requirements. Participants in the control group had unrestricted access to the Internet to gather information regarding breast cancer and was followed up by telephone and recorded by the responsible nurse one week after discharge. However, after completing

Table 1
Summary of the phone-based support program.

Time	Procedure	Activity
Week 0 After obtaining IRB Approval	Preparation: Onsite	- Meeting discharged women for eligibility confirmation and appointment scheduling for each session. Obtained inform consents and measured pre-intervention (T1).
Week 1	Session1: Building relationships (60 min): Onsite	-The PI met participants (one by one). -Discussion the current state of physical and psychological, attitude of life of participants, attitude of life of participants, and strengthening the confidence of participants in privately.
	Session2: Touching PBSP (20 min): Online	Learning group: -Participants shared experiences and prior knowledge about Breast Cancer, symptoms and caring. -Participants saved 10 videos (one video took about 5–7 min). They asked to watch all videos until completed with a week (each video had recording sheets) prior to meet for the next session. 10 videos were watched repeatedly in Breast Cancer Specialist WeChat official account, and a booklet on functional exercise of the affected limb was given 3 months after the operation.
Week 2	Session 3: Coming into your world (30 min): Online	Ask-the-expert group & Discussion group: -Participants asked questions to the expert (an oncologist) what they have learned and were unclear from watching videos. -The PI facilitated questions and answers among participants and the expert. -The participants discussed their problems and learned from the expert.
Week 3	Session 4: Together for a Shared Future (40 min): Onsite	Personal story group & Discussion group: -Participants watched 3 inspiring video-recorded encouraging stories to enhance the women's vicarious experience. -Participants had reflected the videos and whole activities -The PI supported, encouraged, and thank all participants.

the study data collection, the researcher provided them with access to PBSP-related materials. Participants in both intervention and control groups received a routine care.

2.6. Procedures

The PI along with two research assistants, conveyed the details of participation in the study. The PI outlined the measures taken to maintain confidentiality throughout the research process. Prior to their involvement, all participants were required to sign a consent form. The assessment time points were before intervention (baseline [week0-T1]; Day of hospitalization for chemotherapy), immediately after intervention [week3-T2], and follow-up[week7-T3]. General and cancer-related information were gathered at pre-intervention. Participant enrollment and stages of the trial were illustrated in Fig. 1 of the CONSORT flow diagram.

2.7. Measures

2.7.1. Participants' characteristics and outcome measures

Before the intervention, participants filled in a survey on their demographic and clinical characteristics: Part 1 described the participants' general information, such as age in years, relationship with spouse, education, employment status, and family income per month (in USD).

Part 2 described the health information of the participants, including stage of the cancer, the current stage of TNM, type of surgery, and chemotherapy scheme.

2.7.2. Primary outcome: Self-care self-efficacy

The Self-Care Self-Efficacy Scale (SCSES), created by Riegel et al. (2018), serves as an instrument for assessing self-care self-efficacy among individuals dealing with chronic illnesses. Three specific areas focus on maintaining physiological stability, tracking behavior and interpreting changes in symptoms, and managing health changes to prevent illness exacerbation. A higher score on the SCSES suggests better self-efficacy. The scale was translated into Chinese and validated in a previous study with a Chinese sample, achieving a content validity index of 0.91 and a single factor loading of 0.89 (Yu et al., 2021). In this study, the Chinese version of the SCSES had a Cronbach's alpha reliability of 0.89 indicating high reliability.

2.7.3. Secondary outcomes: Symptom distress

Cleeland et al. (2000) developed the M. D. Anderson Symptom Inventory (MDASI) to assess the intensity of symptoms in cancer patients and how these symptoms affect daily life. The MDASI evaluates 13 symptoms and six interference items, using a self-report scale from 0 (not present) to 10 (worst). The total possible score ranges from 0 to 130, with higher scores indicating greater symptom burden. Zhang et al.

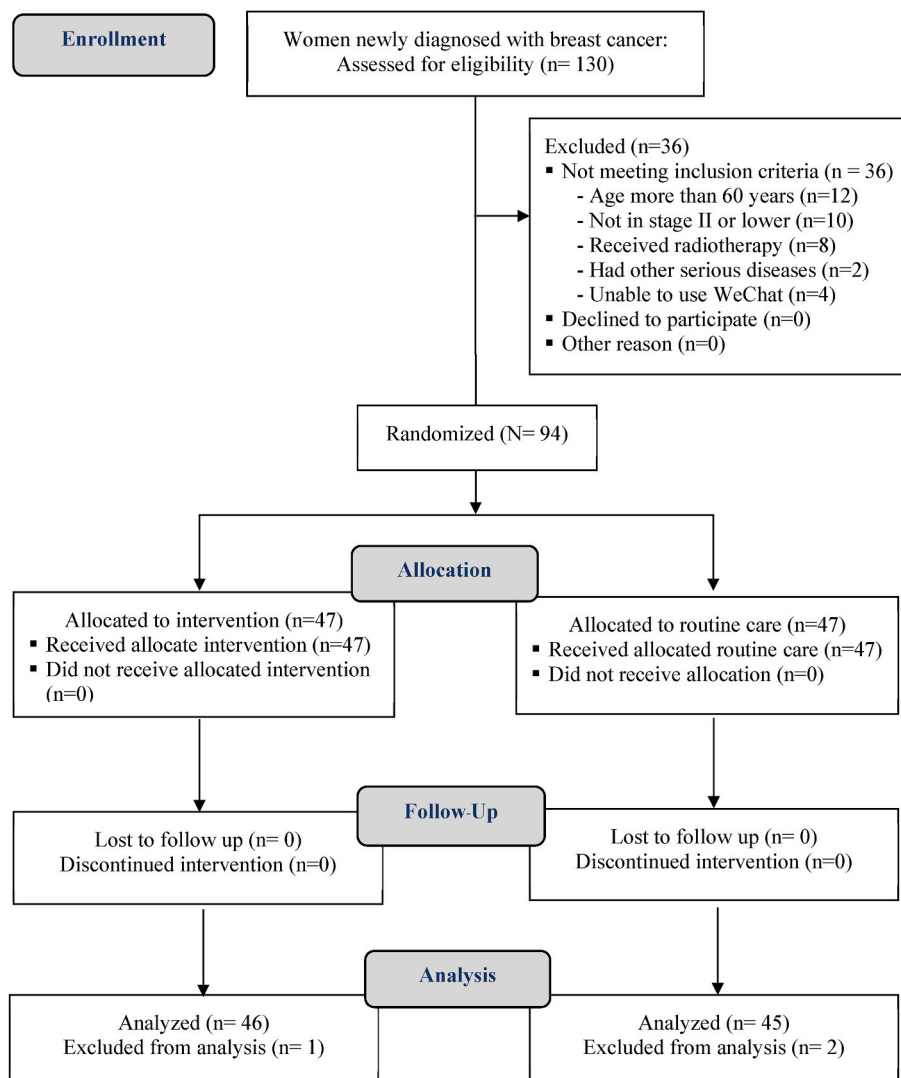


Fig. 1. The CONSORT flow diagram.

(2021) translated this scale into Chinese, reporting reliability values of 0.74 for the symptom subscale and 0.88 for the interference subscale. Our investigation presented a Cronbach's alpha of 0.85 among the Chinese participants.

2.7.4. Secondary outcomes: Anxiety and depression

The tool for evaluating anxiety and depression in healthcare contexts, known as the Hospital Anxiety and Depression Scale (HADS), was adapted into Cantonese and Chinese by Lam et al. (1995). Comprising 14 items divided evenly into sections assessing anxiety and depression, this questionnaire employs a 4-point Likert scale ranging between 0 and 3, yielding potential subscale scores from 0 to 21, where elevated scores correlate with increased anxiety or depressive symptoms (Leung et al., 1999). The HADS boasts robust reliability and validity, particularly pertinent to breast cancer survivor populations. When translated into Chinese, the reported Cronbach's alpha coefficients reached 0.81 for anxiety and 0.72 for depression segments (So et al., 2010). Nevertheless, within our research context, the Cronbach's alpha for the Chinese HADS was observed to be 0.70.

2.7.5. Secondary outcomes: quality of life

The European Organization for Research and Treatment of Cancer (EORTC) (Fayers et al., 2020) created a quality of life (QOL) assessment tool for cancer patients, named the QLQ-C30. Version 3, the most recent, includes 30 items organized into four subscales: (a) Functional (15 items), (b) Symptom (7 items), (c) Side Effects (6 items), and (d) Global QOL (2 items, specifically items 29 and 30). Items 1–28 are rated ranging from 1 to 4, while items 29–30 are scored on 1–7. The higher the total scores (for items 1–28) indicate better health for the functioning and better global QOL (for items 29–30), and all scores are converted to a 0–100 scale to reflect improved QOL. Test-retest reliability for most subscales exceeded 0.80, according to Wan et al. (2008), except for appetite loss (0.77) and diarrhea (0.75). For the QLQ-C30, this scale has a total of 30 items, of which 28 items reflect the specific situations in the lives of cancer patients, and the item 29–30 present the global quality of life of cancer patients (Motzer et al., 2022). Thus, we conducted data analysis on the scores of 28 items, expecting to have a more detailed understanding of the sample's quality of life. Cronbach's alpha reliability was 0.80 in our study.

2.8. Statistical analysis

Data analyses utilized a statistical software program (IBM SPSS version 26.0) with a significance level of $p < .05$. Descriptive statistics, comprising averages, standard deviations, and percentages, describing participants' characteristics of both general and clinical, primary and secondary outcomes. Two-way repeated measure ANOVAs were run to examine the differences of outcome variables among three time-measures.

2.9. Quality control and support for intervention implementation

For the intervention, its contents and protocol were approved by three experts including one is breast surgery specialists in China, one professor is from advanced practical nurses, one professor is from Thailand. They considered and validated the intervention programs. Then, the pilot study was carried out to assess the feasibility of the PBSP (Chen et al., 2024).

Before the implementation of this study, the hospital and relevant department were contacted to obtain consent. A trusting relationship with the participants was established. Data collection and progress were regularly summarized, and timely adjustments and modifications were made as needed. The survey data was collected by research assistants who were uniformly trained. The research assistants need to be familiar with the content of the questionnaire and clear research objectives and can guide patients with breast cancer to fill it out individually. When the

participant completed all questionnaires, the research assistants checked the completeness of the questionnaire and thank the participant for their participation. Participants may ask any questions about the study to the research assistants. Before data analysis, all questionnaires were coded, two-person data entry was used, and data analysis was completed by professionals to ensure the authenticity as well as the objectivity of the data.

2.10. Ethical considerations

The data collection was started after obtaining IRB approval from Burapha University Ethics Committee for Human Research (#G-H103/2565) and the Ethics Review Committee of the first people's hospital of Yancheng (#2022-K-103). The study was prospectively registered with the Thai Clinical Trial Registry #TCTR20230321010.

3. Results

3.1. Attendance and attrition

One hundred and thirty accessible populations were assessed for eligibility criteria and invited to participate in the research project, and 36 patients were excluded. Those of the exclusion included their age were more than 60 years old (12), not in Stage II or lower (10), received radiotherapy (8), had other serious diseases (2), and unable to use WeChat (4). Eventually, 94 participants were remaining and willing to participate. They were randomly assigned equally to the intervention and the control groups (47 cases per group). There was no participant drop-out or loss during the implementation and follow-up period. After testing all assumptions for subsequent statistical analyses, three outliers were removed. There were one (case # 19) in the intervention group and two outliers (cases # 56 and # 73) in the control group. Finally, the total participants in the intervention group were 46, and 45 in the control group. Details were shown in Fig. 1.

3.2. The demographic characteristics of the participants

Among all participants, a mean of 48.21 ± 7.36 years, the age range was from 29 to 60 years. Over 80% patients lived together with spouse. The general and clinical characteristics of the patients indicated comparable profiles between the two groups as detailed in Table 2.

3.3. Descriptive statistics of outcomes at three-time measures

Scores of self-care self-efficacy, symptom distress, hospital anxiety and depression and the QLQ between the intervention and the control groups at pre-intervention (T1), post-intervention (T2), and follow-up (T3) were measured. Their means and standard deviation are shown in Table 3.

3.4. Primary and secondary outcomes

3.4.1. Primary outcome: self-care self-efficacy

The analysis from the two-way repeated-measures ANOVA demonstrated a substantially larger enhancement in self-care self-efficacy among the intervention group compared to the control group. It had a significant interaction effect of Group*Time ($F(1.09, 47.67) = 387.53$, $p < 0.001$, partial $\eta^2 = 0.90$) (Table 4). The simple main effects and Bonferroni-corrected pairwise comparison were tested the differences of each pair of time measures between the two groups, and within the group between time changes. At baseline (between T1), a non-significance was found. The results showed significant differences between post-intervention (T2) (Means = 34.07 and 22.58; $F(1,44) = 430.92$, $p < .001$, partial $\eta^2 = 0.91$) and follow-up (T3) (Means = 45.46 and 23.13; $F(1,44) = 1253.28$, $p < .001$, partial $\eta^2 = 0.97$, respectively). For within the intervention group, the scores of self-care self-efficacy, at

Table 2
Descriptive statistics of participants' characteristics.

Characteristic	Intervention group (N = 46)		Control group (N = 45)		t	χ^2	P value
	n	%	n	%			
	Age (years)						
Average (SD)	48.09 (±8.25)		50.59 (±6.10)		-1.64		0.11
Range	29–59		33–60				
Relationship with spouse							
Living together (married)	35	76.08	39	86.67		1.68	0.19
Non-spouse living (Single, divorced or widowed)	11	23.92	6	13.33			
Education							
Less than HS	24	52.17	22	48.89		0.12	0.94
High school or diploma	10	21.74	10	22.22			
Some college or higher education	12	26.09	13	28.89			
Employment status							
Employed	20	43.48	28	62.22		3.21	0.07
Unemployed	26	56.52	17	37.78			
Monthly family income (in USD)							
Less than 500	24	52.17	27	60.00		0.57	0.45
500 or more	22	47.83	18	40.00			
Breast cancer stage							
I	5	10.87	7	15.56		0.44	0.51
II	41	89.13	38	84.44			
TNM							
T1N1M0	4	8.70	6	13.33		5.12	0.08
T2N1M0	24	52.17	26	57.78			
T2N0M0	18	39.13	13	28.89			
Surgery type							
Modified radical mastectomy	38	82.61	42	93.33		2.46	0.12
Laparoscopic unilateral radical mastectomy	8	17.39	3	6.67			
Chemotherapy scheme							
AC-T	34	73.91	35	77.78			
TAC	4	8.70	6	13.33		1.74	0.42
TC	8	17.39	4	8.89			

Abbreviations: The TNM system for cancer staging involving the tumor (T), node (N), and metastases (M).

T1: The tumor is 20 mm (2 cm) in diameter or less. **T2:** The tumor is larger than 20 mm but not larger than 50 mm. **N0:** No cancer was found in the lymph nodes/ Only areas of cancer smaller than 0.2 mm are in the lymph nodes. **N1:** The cancer has spread to 1 to 3 axillary lymph nodes and/or the internal mammary lymph nodes. If the cancer in the lymph node is larger than 0.2 mm but 2 mm or smaller. **M0:** There is no evidence of distant metastases. **TC:** docetaxel + cyclophosphamide, 4 cycles.

post-intervention (T2) and follow-up (Week 7, T3) were significantly higher than that at baseline (T1) ($M_{diff} = 11.00$ and $M_{diff} = 22.39$, $p < 0.001$, respectively), and the scores at follow-up (T3) was significantly higher than that at post-intervention (T2) ($M_{diff} = 11.39$, $p < 0.001$) (Fig. 2). There was no pair of time difference in the control group ($p > .05$). These findings showed that after receiving the PBSP, participants in the intervention group had better self-care self-efficacy than the control group and could maintain this effect over time.

3.4.2. Secondary outcomes: Symptom distress, anxiety, depression and quality of life

Two-way Repeated measures ANOVA also showed results of symptom distress, anxiety, depression and quality of life. All the secondary outcomes presented a pronounced interaction effect of Group*Time: Symptom distress ($F(1.71, 75.37) = 109.78$, $p < 0.001$, partial $\eta^2 = 0.71$), hospital anxiety ($F(2, 88) = 35.72$, $p < 0.001$, partial $\eta^2 = 0.45$), hospital depression ($F(2, 88) = 64.94$, $p < 0.001$, partial $\eta^2 = 0.60$), and

Table 3
Means and standard deviations of the study outcomes for the intervention and the control groups at three time periods.

Outcome	Time	Intervention (N = 46)		Control (N = 45)	
		Mean	SD	Mean	SD
Self-care self-efficacy	Time 1	23.07	2.82	22.07	3.32
	Time 2	34.07	2.82	22.58	2.07
	Time 3	45.46	2.61	23.13	3.16
Symptom distress	Time 1	94.35	17.53	96.98	11.77
	Time 2	67.63	9.61	94.31	11.15
	Time 3	38.91	7.06	93.67	13.75
HADS anxiety	Time 1	11.24	2.66	10.89	1.92
	Time 2	7.59	2.69	10.11	1.94
	Time 3	4.89	1.64	10.00	2.52
HADS depression	Time 1	11.33	1.83	11.27	2.16
	Time 2	7.50	2.54	11.11	2.54
	Time 3	3.65	1.57	10.36	2.30
Quality of life	Time 1	68.89	5.39	68.96	5.54
	Time 2	79.15	5.45	70.97	7.35
	Time 3	88.94	4.40	71.75	5.43

Time: Baseline (week 0, T1), post-intervention (week 3, T2), and follow-up (week 7, T3).

quality of life ($F(1.73, 75.96) = 61.63$, $p < 0.001$, partial $\eta^2 = 0.58$) (Table 4).

Subsequently, the simple main effects and Bonferroni-corrected pairwise comparisons were also run to examine the difference between groups at each time point, and within group between each pair of times. Psychological distress scores of symptom distress, anxiety and depression were significant differences at post-intervention (T2) and follow-up (T3) between the two groups, but not at baseline.

For symptom distress, both time-measures at post-intervention (Week 3, T2), and at follow-up (Week 7, T3), the intervention participants had significantly lower symptom distress than that in the other participants (T2, Means = 67.63 and 94.31; $F(1,44) = 131.30$, $p < .001$, partial $\eta^2 = 0.75$, and T3, Means = 38.91 and 93.67; $F(1,44) = 632.84$, $p < .001$, partial $\eta^2 = 0.94$; respectively) (Fig. 3). For within the intervention group, the MDASI scores at Time 2 and Time 3 were significantly lower than that at baseline ($M_{diff} = 26.72$ and $M_{diff} = 55.43$, $p < .001$, respectively), and the scores at Time 3 was significantly lower than that at Time3 ($M_{diff} = 28.72$, $p < 0.001$) (Fig. 3).

For hospital anxiety and depression, both scores at Time 2 and Time 3 of the intervention participants were significantly less than that in the other group [(T2, anxiety mean scores = 7.59 and 10.11; $F(1,44) = 20.52$, $p < .001$, partial $\eta^2 = 0.32$, and T3, anxiety mean scores = 4.89 and 10.0; $F(1,44) = 193.82$, $p < .001$, partial $\eta^2 = 0.82$, respectively) (Fig. 4) and (T2, depression mean scores = 7.50 and 11.11; ($F(1,44) = 49.48$, $p < .001$, Partial $\eta^2 = 0.53$, and T3, depression mean scores = 3.65 and 10.36; $F(1,44) = 253.89$, $p < .001$, Partial $\eta^2 = 0.85$, respectively)] (Fig. 5).

For within the intervention group, the hospital anxiety and depression scores at post-intervention and follow-up were significantly lower than that at baseline (anxiety: $M_{diff} = 3.65$ and $M_{diff} = 6.35$, $p < 0.001$, respectively, and depression: $M_{diff} = 4.44$ and $M_{diff} = 8.28$, $p < 0.001$, respectively), and the scores at follow-up was significantly lower than that at post-intervention (anxiety: $M_{diff} = 2.70$, $p < 0.001$, and depression: $M_{diff} = 3.85$, $p < 0.001$) (Figs. 4 and 5).

The QOL scores at baseline found no difference between both groups ($p > .05$). At post-intervention (Week 3, T2), and at follow-up (Week 7, T3), scores of QLQ in the intervention group were significantly higher than that in the control group (T2, means = 79.15 and 70.97; $F(1,44) = 41.20$, $p < .001$, Partial $\eta^2 = 0.48$, and T3, means = 88.94 and 71.75; $F(1,44) = 332.86$, $p < .001$, Partial $\eta^2 = 0.88$, respectively). The QOL scores in the intervention group at Time 2 (post-intervention) and Time 3 (follow-up) were significantly greater than that at Time 1 (baseline) ($M_{diff} = -10.37$ and $M_{diff} = -20.05$, $p < 0.001$, respectively), and the scores at follow-up was significantly higher than that at post-

Table 4

Comparisons of the outcomes between the intervention and the control groups and within the intervention group for time and the interaction between time and group.

Source variation	SS	df	MS	F	p-value	η^2p
Self-care Self-efficacy^a						
Between Subjects						
Group	9140.89	1	9140.89	606.08	<.001	0.93
Error	663.61	44	15.08			
Within subjects						
Time	6172.36	1.26	4906.16	740.06	<.001	0.94
Error	366.98	55.36	6.63			
Group*Time	5099.05	1.08	4707.22	387.53	<.001	0.90
Error	578.95	47.66	12.15			
Symptom distress^b						
Between Subjects						
Group	52780.09	1	52780.09	249.23	<.001	0.85
Error	9318.07	44	211.77			
Within subjects						
Time	39223.70	2	19611.85	160.74	<.001	0.79
Error	10736.97	88	122.01			
Time*Group	30951.79	1.71	18068.53	109.78	<.001	0.71
Error	12405.55	75.37	164.59			
HADS anxiety^b						
Between Subjects						
Group	393.62	1	393.62	75.39	<.001	0.63
Error	229.72	44	5.22			
Within subjects						
Time	602.36	1.60	376.49	70.94	<.001	0.62
Error	373.64	70.40	5.31			
Group*Time	339.03	2	169.52	35.72	<.001	0.45
Error	417.64	88	4.75			
HADS depression^b						
Between Subjects						
Group	713.78	1	713.78	173.47	<.001	0.80
Error	181.05	44	4.12			
Within subjects						
Time	943.03	2	471.52	146.98	<.001	0.77
Error	282.30	88	3.21			
Group*Time	610.81	2	305.40	64.94	<.001	0.60
Error	413.86	88	4.70			
Quality of life^a						
Between Subjects						
Group	4689.66	1	4689.66	159.50	<.001	0.78
Error	1293.71	44	29.40			
Within subjects						
Time	5873.26	2	2936.63	119.18	<.001	0.73
Error	2168.44	88	24.64			
Time*Group	3350.68	1.73	1940.91	61.63	<.001	0.58
Error	2392.32	75.96	31.50			

η^2p = partial Eta Squared.

^a Greenhouse-Geisser was used to adjust the degree of freedom.

^b Huynh-Feldt was used to adjust the degree of freedom.

intervention ($Mdiff = -9.78, p < 0.001$) (Fig. 6).

The participants who received the PBSP had less psychological distress and better quality of life than that in the control group and could maintain these effects overtime to the follow-up period.

4. Discussion

This single-blind randomized-controlled trial demonstrates that participation in the PBSP led to increased SCSE and enhanced QOL for patients. In addition, people exhibited decreased symptoms distress, anxiety and depression in the post-program and at the 7-week follow-up. Conversely, the control group did not exhibit significant changes in these outcomes. These findings suggest that the PBSP presents a promising approach for improving the well-being of individuals with breast cancer, with potential applications in both clinical and community settings.

The PBSP could enhance the self-care self-efficacy for patients with breast cancer. At present, there are several researches on linking self-care self-efficacy. However, most of studies addressed on self-efficacy.

This finding is similar consistent with the effectiveness of educational mobile application that improved self-care, self-efficacy and knowledge among adult patients with hypertension (Dwairej and Ahmad, 2022). Self-care is a specific condition of self-efficacy. The PBSP which stabilizes the inner confidence strength the patients' capability of performing self-management tasks required to effectively cope breast cancer. PBSP is precisely because of this interaction, that the patient's self-care self-efficacy is improved.

The large effect sizes in the results of our study support that women who participated in the PBSP also reported decreased symptoms distress, hospital anxiety and depression among people with dementia. After patients learned knowledge and skills for responding to the challenging symptoms of people with breast cancer under chemotherapy, which can result in decreased symptoms and improved the quality of life. Moreover, the results also showed an increase in the quality of life of participants who newly diagnosed with breast cancer undergoing chemotherapy in the intervention group. The results have confirmed that the PBSP is effective in that it helps enhance quality of life among breast cancer women.

Multiple factors might account for these significant effect sizes. Primarily, the program was designed using self-efficacy theory and relevant literature reviews. The primary objective of the program was to enhance patients' self-efficacy. The program recorded high levels of attendance and participation. Self-efficacy is a crucial concept influencing symptom distress outcomes in breast cancer patients across all treatment stages. It refers to an individual's belief in their ability to perform behaviors necessary to achieve desired outcomes (Schunk and DiBenedetto, 2021). Patients should have self-manage their symptoms to reduce symptoms of distress but may have not enough self-efficacy to do so. Patients who participated in the PBSP also reported decreased symptoms distress among people with breast cancer. The PBSP used the WeChat, an application for online social connection using widely and commonly in China, to improve cancer patients' self-efficacy and that improved patients' symptom management capabilities to reduce the impact of cancer-related symptoms on their lives. In usual daily life, breast cancer patients are primarily responsible for managing their own health, and they must be able to implement specific behaviors for symptom management tasks, such as symptom recognition, prevention, and actions to reduce or alleviate symptom intensity, duration, and frequency (Saeidzadeh et al., 2021). In the learning group of PBSP, the researcher and breast-related medical experts developed a video push on the theme of common symptoms. The main purpose was to teach patients to monitor their own symptoms and deal with the basic symptoms that appear at that time, so as to avoid unnecessary panic. At the same time, they could communicate with the attending doctor at any time. The PBSP has increased patient's knowledge awakens and subconscious mind in fighting the disease, and at the same time created a platform for patients to socialize, thereby decreasing the patient's symptom distress.

Second, the PBSP represents the first intervention in China utilizing a smartphone app to enhance patients' self-efficacy in self-care. Through the WeChat app, patients could quickly access breast cancer information, providing a tool for managing symptom distress as it arose. The app also allowed them to seek assistance from peers in the intervention group. Participants could join a social media group via their smartphones to share and discuss their care experiences, interact for mutual encouragement, and offer emotional support, potentially alleviating anxiety and depression. However, typical face-to-face therapies may not be suitable for many cancer patients due to accessibility difficulties such as clinic location, travel duration, and inter-changeability. The PBSP provided a place for breast cancer patients to express their emotions via the WeChat online platform and peer groups. After getting along in the online social group, they become like relatives. They not only communicated in the WeChat group, but also communicate face to face in the ward when they were admitted to the hospital at the same time. In addition, breast medical specialists join the PBSP in every week, which is very beneficial for patients to relieve anxiety and depression. Several

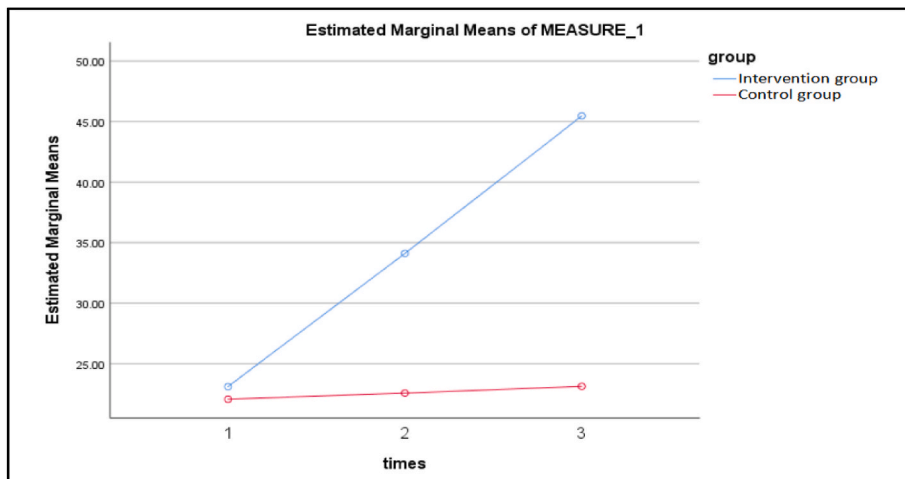


Fig. 2. Comparisons of means of total SCSE scores between the intervention and the control groups, and among 3-time measures.

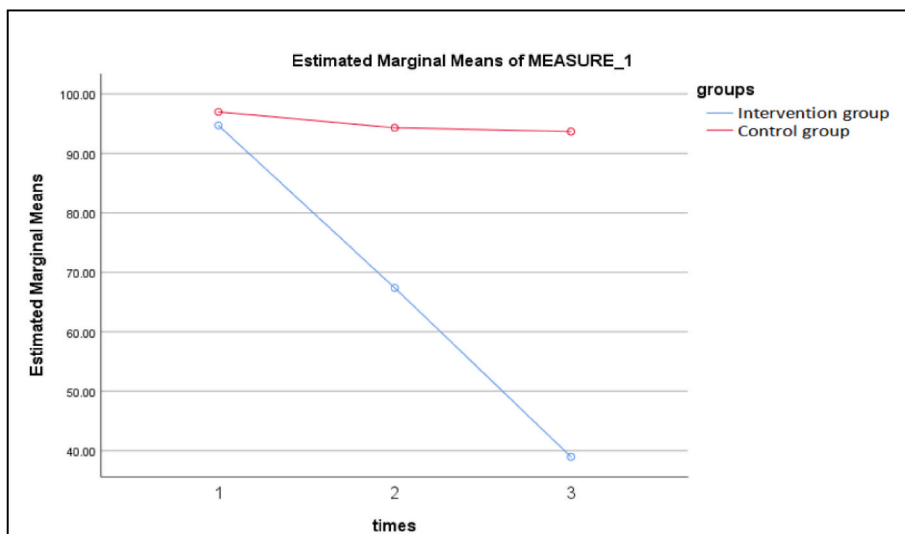


Fig. 3. Comparisons of means MDASI scores between the intervention and the control groups, and among 3-time measures.

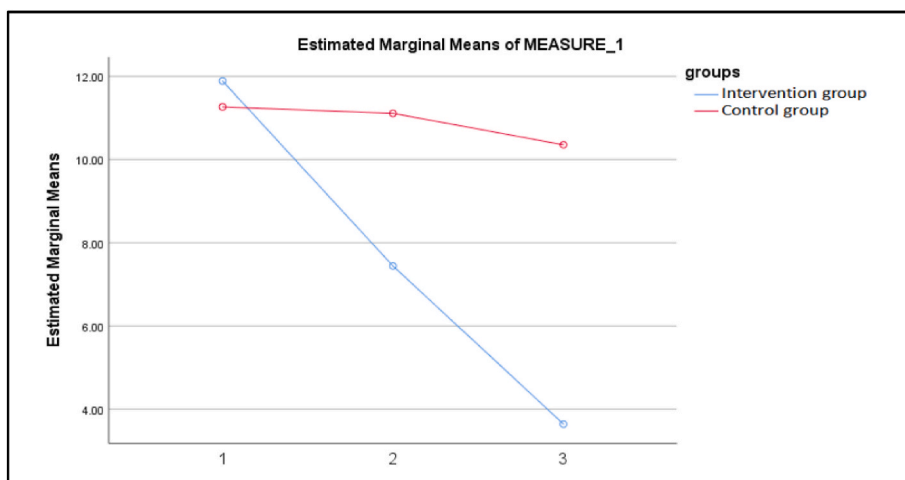


Fig. 4. Comparisons of means hospital anxiety scores between the intervention and the control groups, and among 3-time measures.

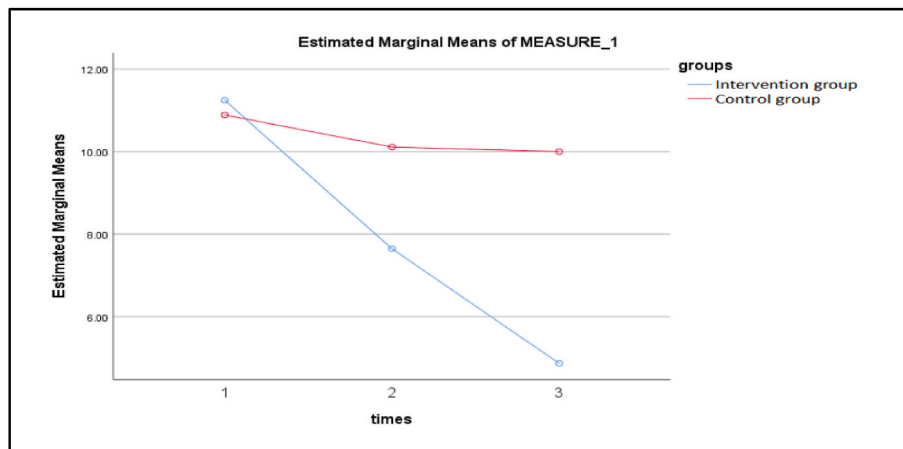


Fig. 5. Comparisons of means hospital depression scores between the intervention and the control groups, and among 3-time measures.

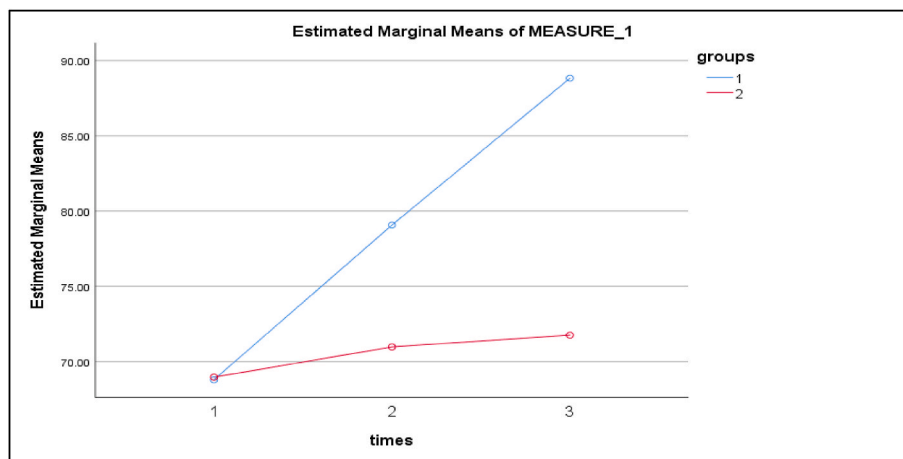


Fig. 6. Comparisons of means QoL scores between the intervention and the control groups, and among 3-time measures.

previous studies have found similar to these findings. Brog et al. (2022) investigated the effects of Internet-based educational interventions on depression, statistical results showed significant in distress. Børø Sund et al. (2014) found that an Internet-based patient-provider communication service (IPPC) not only significantly reduced depression compared to usual care but also had further positive effects on symptom distress, anxiety, and depression. This suggests the potential of e-technology in empowering patients to manage their symptoms occurred from the cancer treatment. These prior findings were consistent with the results of our study. Wong et al. (2022) showed that social support has a substantial correlation with self-care self-efficacy. Actually, after being diagnosed with cancer, some patients become socially isolated and are afraid to share the illness or participate in social activities. This circumstance may impede the patients' information searching. The PBSP is a major source of practical and emotional support that put together individuals with the same illness.

Third, the 3-week program length proved manageable for the participants. Their completion of the entire intervention demonstrates a strong motivation to enhance their understanding and self-efficacy. Overall, our results are consistent with studies of Zhu et al. (2020), they found that an application program (App) could promote women with breast cancer's self-efficacy, social support and symptom management, thus improving their quality of life and psychological well-being.

The PBSP used the WeChat as a mean to deliver a whole caring for patients. It is a bridge between home and hospital. Using the WeChat platform to provide prolonged care for breast cancer patients following

surgery might assist doctors and nurses in managing patients' post-discharge situations. Sending PBSP videos over WeChat might assist patients better comprehend the relevant medical information, improve their adherent and attention to nursing, and boost patients' self-assurance in their ability to fight the condition. Furthermore, the WeChat platform has a call video capability, which allows for more immediate contact between physicians and patients in the Ask-Expert group. Moreover, it promoted physical recovery by stimulating patients to regulate consciousness, relaxation, sleep, exercise, nutrition, medication, and other aspects, so as to help them achieve an optimistic attitude to confront the disease. Therefore, the PBSP supply the new thoughts for clinical nurse to carry out full-process and systematic care. The PBSP presents an independence that can enrich life and enhance the women's quality of life. The Chinese participants enjoyed applying it, and they can enter the groups related their needs. The PBSP assisted the participants as an interventional tool for the self-management of symptoms. They also can catch the most suitable information medical-related guidance automatically for self-care. This enhanced patient operative competence and self-efficacy, resulting in a higher quality of life, according to Bandura's self-efficacy hypothesis.

4.1. Limitations

The threat of data contamination may occur due to some cases of participants in both groups living in the same department at the same time. Although the researchers used the PBSP to isolate the participants of the intervention groups in separate rooms. Communication between

the two groups was possible. In addition, this study was conducted in one setting in China; therefore, it limited generalizability to other settings with different contexts. This study did not consider about the participants' underlying medical conditions, which may limit the general applicability and depth of analysis of the research findings.

5. Conclusion

The PSBP is effective on enhancing self-care self-efficacy and quality of life, and lessen psychological distress in newly diagnosed breast cancer who were receiving chemotherapy comparing between the intervention and the control groups. Moreover, within the intervention group, the changes were improved overtime. Then provide the rationale that can achieve this effectiveness, as participants engaged more with the PSBP and experienced its benefits, their self-efficacy and subsequent self-care behaviors improved. The continuous interaction with the app likely provided ongoing mastery experiences, vicarious learning, verbal persuasion, and emotional arousal, enhancing their confidence and ability to manage their health. The increase in self-efficacy leads to better self-care self-efficacy. By showing that enhanced self-efficacy leads to better self-care self-efficacy. This confidence is crucial for patients to engage in consistent self-care behaviors such as maintenance (keeping up with treatment and health routines), monitoring (being aware of changes in their condition), and management (actively addressing health issues). These behaviors are essential for managing a chronic and challenging condition like breast cancer. By empowering patients through improved self-care self-efficacy, the PSBP helps in reducing symptoms of distress, anxiety, and depression. As patients feel more capable of managing their health, their overall quality of life improves.

Trail registration number

Thai Clinical Trial Registry: #TCTR20230321010 (registration date: 21 March 2023; first recruitment date: 7 April 2023).

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CRedit authorship contribution statement

Xi Chen: Writing – original draft, Visualization, Validation, Resources, Methodology, Investigation, Funding acquisition, Formal analysis, Data curation, Conceptualization. **Yang Qin:** Writing – review & editing, Writing – original draft, Visualization, Formal analysis, Data curation. **Nujjaree Chaimongkol:** Writing – review & editing, Visualization, Supervision, Project administration, Methodology, Conceptualization.

Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Nujjaree Chaimongkol reports a relationship with Burapha University Faculty of Nursing that includes: employment. If there are other authors, they declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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