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Long-term effectiveness of an E-based survivorship care plan for breast cancer survivors: A quasi-experimental study

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ABSTRACT

Objective: The purpose of this study was to evaluate the effect of a web-based survivorship care plan (SCP) computerized application (APP): (SCP-A) on women's unmet needs, fear of recurrence, symptom distress, anxiety, depression, and quality of life (QoL).

Methods: Women diagnosed with breast cancer, who had completed their primary treatment but less than 5 years without a sign of recurrence (N = 165) were randomized to a SCP-A or a control group. Self-reported questionnaires were completed by the both groups at baseline (T0), 5 weeks (T1), 3 months (T2), 6 months (T3), and 12 months (T4).

Results: Controlling for relevant covariates, mixed effect model analyses revealed a significant decrease in women in the SCP-A group compared to the control group for total unmet needs since T3 ($p < .004$) and fear of recurrence since T4 ($p = .02$). Women in the SCP-A group also reported significant improvements in QoL at T4 ($p < .001$) relative to those in the control group.

Conclusion: Providing SCP using an information website application for women with breast cancer can decrease unmet needs, fear of recurrence, and improve quality of life during short-term and long-term use.

Practice Implications: Web-based information that provides survivorship care plans for breast cancer survivors are beneficial.

1. Introduction

Women with breast cancer face a variety of difficulties and challenges that do not end after treatments are completed. The late and long term effects of cancer treatments include physical and psychological symptoms such as pain, lymphedema, osteoporosis, depression, anxiety, and fear of recurrence [1]. Each of these symptoms can impact quality of life [1–3] and result in unmet needs, including a need for information on ways to decrease physical /psychological side effects, adapt to a role as a cancer survivor, reduce the possibility of recurrence, and sustain an intact body image [4]. The rate of unmet needs is higher for women with breast cancer compared to other gynecological cancers or mixed cancer populations [5], a finding which underscores the importance of improved survivorship care for women with breast cancer.

Over the last decade, survivorship care plans (SCPs) have been recommended as the standard of care for cancer patients. According to the Institute of Medicine (IOM), SCPs include providing information related to cancer prevention, examination, and detection, while also suggesting ways to delay the late and long term side effects of treatment. In a systematic review of outcomes after implementing SCP, Brennan and colleagues (2014) identified 10 studies, five of which measured the quality of life of breast cancer survivors. None of these studies reported a sustained benefit to quality of life [6]. Limited effects on quality of life may be due to the fact that these patients had received treatment evaluations but had not undergone an individual needs assessment before the provision of an SCP. Researchers have suggested the use

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of personalized SCPs to meet the individual needs of cancer survivors [7–9]. As a result, designing individualized SCPs could be an effective means by which to improve quality of life of breast cancer survivors.

The Internet has become an important source of health management information for cancer survivors [10]. The Internet is private, widely accessible, and available to most breast cancer survivors who desire to obtain health information [11]. Individual needs can be considered using a design with a navigation function that uses an icon allowing cancer survivors to obtain desired information [12]. A study surveyed the web-based SCP intervention on a mixed-cancer population and reported that 45% of the users were women with breast cancer [13]. Therefore, the purpose of this study was to develop and test a web-based SCP for women with breast cancer in Taiwan. Because patient outcomes typically only focus on survival rates rather than on the psychosocial needs of these patients [8], the primary outcome is unmet needs, and the secondary outcomes in this study are fear of recurrence, symptoms, depression, anxiety, and quality of life.

2. Methods

2.1. Participants

After obtaining Institution Review Board approval, patients were recruited from a single medical center in Southern Taiwan. Women were eligible for participation if they were 20 years or older and had been diagnosed with breast cancer within the last 5 years. Women were included if their primary treatment had been completed with no sign of recurrence, and they were able to speak Mandarin or Taiwanese. Participants in the intervention group were required to own a smart phone or tablet with an Android system. Women were excluded if they reported severe medical, psychiatric, or cognitive illnesses that would prevent participation.

2.2. Intervention vs. usual care

Women allocated to the control group (CG) received usual care from health care providers. They were provided with an educational leaflet with information about timing of follow-up visits, recommended examinations, and special considerations related to years since diagnosis and cancer pathology. They attended routine clinic follow-ups. There were no restrictions related to accessing the Internet or participating in other self-help activities.

Women allocated to the intervention group (IG) were given access to a web-based survivorship care plan (SCP) computerized application (APP): Healthy Living with Breast Cancer (SCP-A). The SCP-A structure was based on the Breast Cancer Survivorship Guidelines recommended by the American Cancer Society and the American Society of Clinical Oncology [14]. Information was presented in 7 modules using texts or videos based on literature conducted in Taiwan identifying the needs of women with breast cancer [4,15,16] (supplemental Table 1). In addition, a push notification reminded women to take their prescribed medicine, participate in a module, seek remedies for side effects, and the date of next outpatient follow-up.

The SCP-A was personalized to each subject. Upon logging onto the website, a woman completed a baseline unmet needs assessment and treatment evaluation. Tailored information based on the side effects of the treatments they received or reported was linked in the module. The researcher aware of each subjects' login information. Individualized relevant information provided in the module by the researcher based on the assessment of unmet needs. The personalized SCP was formulated and printed out for each participant at the clinic. Topics in the modules were introduced individually to the participants each week via a push notification for a period of five weeks. As a result, the 2nd follow-up assessment was administered five weeks later. The website was updated routinely (Supplemental Table 1 & Appendix).

2.3. Instruments

Baseline data collection (T0) included demographic data and clinical data from the medical records of the patients. The E-Health (eHealth) literacy with 8 items was used [17] to determine the ability of the participants to apply electronic health information to health problems. At T0-T4, baseline, 5 weeks, 3, 6, and 12 months, the following five instruments using a paper format were administered.

The Cancer Survivor Unmet Needs-Chinese (CaSUN-C) Scale is assesses the unmet needs of breast cancer survivors [4]. The CaSUN-C includes 20 items related to information, physical /psychological, medical care, and communication needs. Participants indicate if the need is not applicable, met, or unmet. If an unmet need is reported, the intensity of the need is then rated as weak (1), moderate (2), or strong (3). The CaSUN-C is scored from 0 to 60, with higher scores reflecting a higher intensity of unmet needs. The four factor structure has shown acceptable reliability and validity among breast cancer survivors (Cronbach's Alpha = .61 to .82) [4].

The Assessment of Survivors Concerns (ASC), a 5-item scale, evaluates cancer-specific worries about fear of recurrence (CW, 3 items) and general health worries (HW, 2 items) over the past week [18]. Forward and backward translation confirmed that the Chinese version is equivalent in meanings to those of the original items [19]. Response options are on a four-point scale ranging from 1 ("not at all") to 4 ("very much"). The scale is suitable for short and long term survivors with good validity. Internal consistency is high for the CW subscale and acceptable for the HW subscale [18].

The WHOQOL-BREF Taiwan assesses health-related quality of life (HRQoL) includes four domains with 26 items across physical, psychological, social, and environmental health. Two general item questions ask about overall HRQoL and general health. Responses are rated using a 5-point scale, with a high score indicating better QOL. The domain scores are calculated using the mean domain item scores and transformed to a 0–100 scale. The internal consistency ($\alpha = 0.70$ to 0.91) and the test-retest reliability ($r = 0.76$ to 0.80) of the WHOQOL-BREF measurement has been established [20]

The Hospital Anxiety and Depression Scale (HADS) assesses symptoms of anxiety and depression. The HADS includes 14 items, of which 7 measure anxiety, and 7 measure depression. All items are scored using a 0–3 point scale, with higher scores indicating more depressive symptoms. Cut-off scores are used to categorize anxiety and depressive symptoms, with values of over 8 indicating possible anxiety and depression, and 11 or above indicating probable anxiety and depression [21,22].The Chinese version of the scale has been widely used in cancer patients with good reliability and validity for women with breast cancer [23].

The Chinese version of the Memorial Symptom Assessment Scale Short-Form (MSAS-SF) measures symptom distress. The MSAS-SF includes 28 physical and 2 psychological symptoms commonly experienced by cancer patients. Participants are instructed to indicate the symptoms they have experienced over the past week and rate the intensity of their distress on a 5 point scale ranging from "not at all" (0) to "very much" (4). Four subscales, the Global Distress Index (GDI), Physical Symptom Distress, Psychological Symptom Distress, and the Total MSAS score are calculated. The MSAS-SF has been validated and is widely used with Chinese cancer patients [24,25].

2.4. Procedure

Women were referred the study by their outpatient physicians during their regular follow-up visit. After receiving approval to conduct the study from the Institutional Review Board (protocol number B-ER-104-397), the women provided consent and completed the baseline assessment. Consenting women were randomized using an online automated randomization service to determine group allocation. In order to maintain equal sample sizes, the women were randomly assigned using permutated block randomization (allocation ratio 1:1). At 5 weeks (T1), 3 months (T2), 6 months (T3), and 12 months (T4), the women completed the research questionnaires during their routine clinic visit. If clinic visits were not attended, the research questionnaires were mailed to their home. Data were collected from October 2016 to August 2018.

2.5. Data analysis

An intention to treat (ITT) analysis was conducted using SPSS (V. 24) with significance at $p < .05$. Demographic variables were analyzed, and the groups were compared to assess covariates including social-demographic and treatment-related factors. A mixed effects model that included the study group, a categorical indicator of time, and the interaction between group and time was generated after controlling for the covariates (with a significant interaction indicating that compared to CG, the intervention effects change over time). An autoregressive covariance structure analyzed changes among the time points and residual maximum likelihood to estimate the fixed effects. Because there was only a 4% attrition rate, missing data was not imputed, but a REML (restricted maximum likelihood) estimation was used for data management. To correct for multiple testing, the false discovery rate (fdr) method was applied [26].

2.6. Sample size

Based on the limited number studies reporting unmet needs as a primary outcome, a post-hoc power analysis of unmet needs using the Glimmpse online tool (http://glimmpse.samplesizeshop.org) was calculated. The study sample of 165 women who completed the baseline assessment revealed a 99% power.

3. Results

A total of 248 women were approached with 202 completing the baseline questionnaires and were randomly assigned to either the control or intervention group. If a subject was assigned to the intervention group and did not own a cell phone or tablet with an Android system, they were dropped from the study (n = 15). Eighteen subjects dropped out after allocation and prior to the baseline data collection (control = 11, intervention = 7) (Fig. 1). At T4, 151 women provided complete data at each data collection point. At baseline, there were no between-group differences in terms of demographic characteristics and eHealth literacy (Supplemental Table 2). However, more women in the intervention group had received chemotherapy (p = .006).

At baseline, 10.9% of the women (n = 18) had clinical indications of anxiety, while 6.7% (n = 11) exhibited depression according to the HADS score. Given the significant findings suggesting that chemotherapy may have been responsible for more unmet needs, symptom distress, and fear of recurrence ($p = .006$) and the borderline significance of time since diagnosis ($p = .06$), a mixed effects analyses were adjusted for these variables.

3.1. Intervention use

Participants (n = 83) in the intervention group used a mean of 4.5 modules (Range: 1–7; SD = 1.57). In total, 3.6% used one module; 7.2% used two modules, 12% used three modules, 27.7% used four modules, 21.7% used five modules; 14.5% used six modules, and 13.3% used all seven modules. The most viewed module (29.5%) was Living with Side Effects, followed by Healthy Living Everyday (28.85%), Survivor Stories (13.45%), Embracing Breast Cancer (12.85%), Time for Mother and Daughter (6.47%), Complementary and Alternative Medicine (6.06%), and Caregiver, Family, and Friends (2.96%).

3.2. Intervention effect

Fig. 2 provides a summary of the results from the mixed model for the unmet need and secondary outcomes. The two groups differed in terms of unmet needs, fear of recurrence, and symptoms at baseline with the intervention group reporting higher values across these variables (Supplemental Table 3).

3.2.1. Unmet needs

The interaction of time and group reached significance at T3 (ß=-3.34, SE = .97, $P_{ftd} = .004$) to T4 (ß=-3.57, SE = .79, $P_{ftd} = .000$), which indicated that the decrease in total unmet needs from baseline in the intervention group compared to the control group was significant after the 4th month follow-up. The interaction of time and group also reached significance in the domains of physical and psychological effect (T2 to T4), information (T3 to T4), and communication (T4) (Fig. 2 & supplemental Table 3).

3.2.2. Fear of recurrence

Fear of recurrence declined significantly over time for both groups. The interaction of time and group also reached significance, indicating a significant decrease in fear of recurrence from the baseline in the intervention group compared to the control group after the 12th month (T4) follow-up (ß=-1.56, SE = .49, $P_{ftd} = .021$) (Fig. 2 & Supplemental Table 3).

3.2.3. Symptom distress, depression and anxiety

There was a tendency toward a decrease in total symptom distress, total symptom number, depression, and anxiety over time in both groups. However, the interaction of time and group did not reach significance (Fig. 2 & Supplemental Table 3).

3.2.4. Quality of life

There was a tendency toward an increase in the total quality of life over time in both groups. The interaction of time and group reached significance at T4, which indicated that the increase in total quality of life from baseline in the intervention group compared to the control group was significant after the 1 year follow-up (ß = 6.85, SE = 1.76, $P_{ftd} = .000$) (Fig. 2 & supplemental Table 3).

4. Discussion and conclusion

4.1. Discussion

This study examined whether providing access and use of a web-based SCP-A for breast cancer survivors reduced unmet needs, symptom distress, fear of recurrence, and improved QoL. Though subjects were randomized, differences were found in symptom distress, unmet needs, and fear of recurrence between the groups at baseline. Women in the IG reported a significantly higher incidence of chemotherapy. It is possible that the chemotherapy regimen contributed to these differences [27,28].

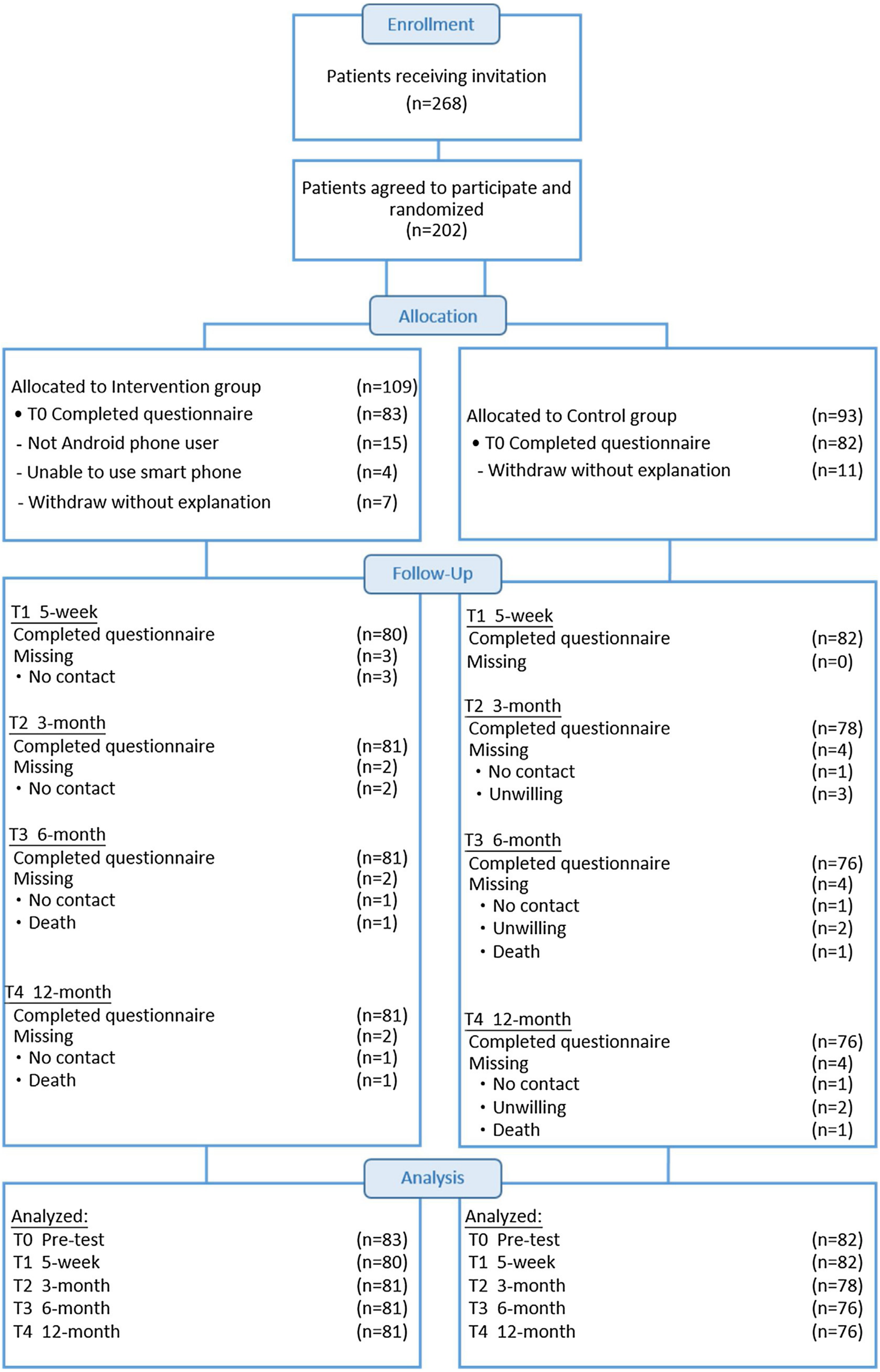

Fig. 1. Flow diagram of the study.

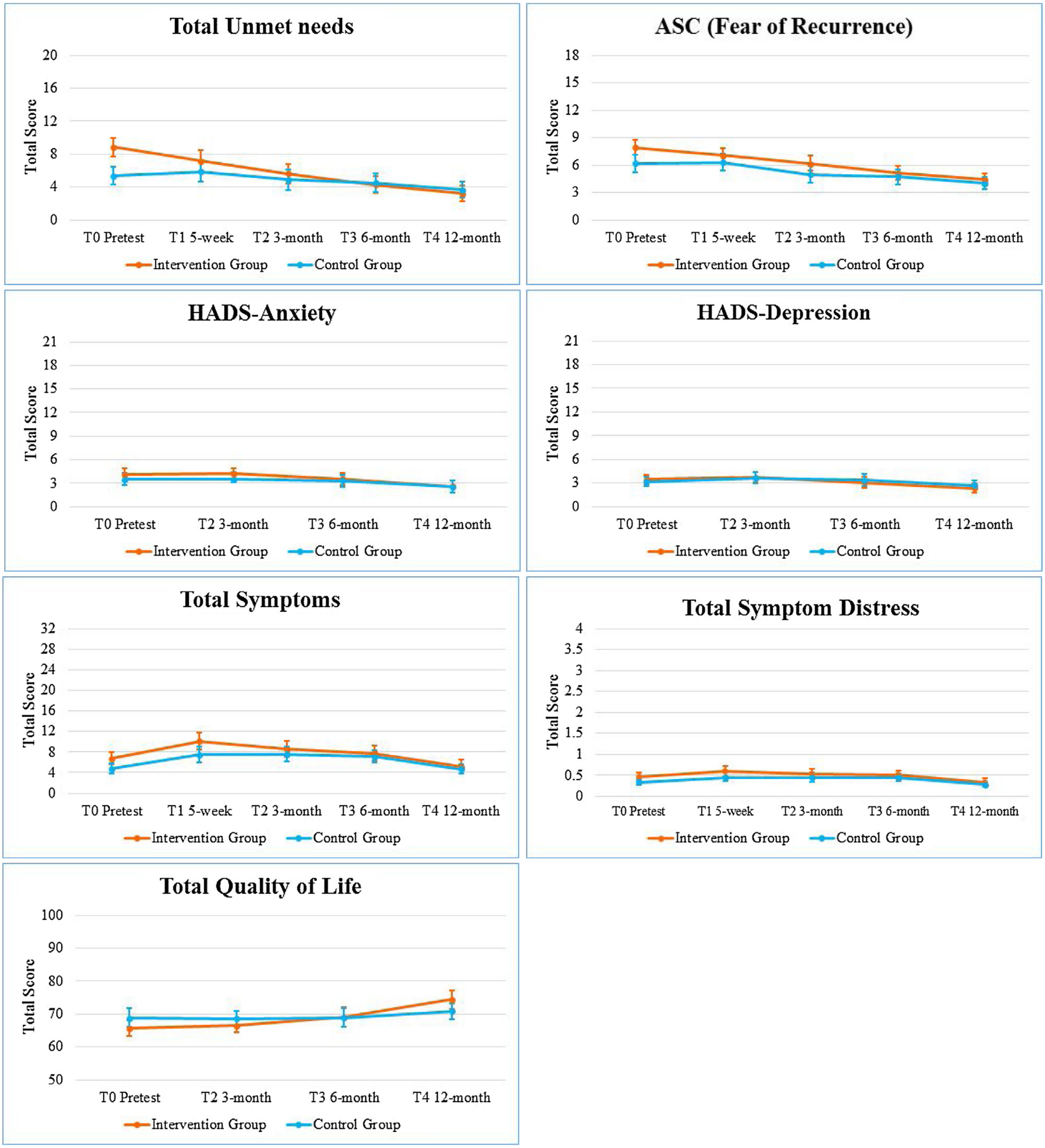

Fig. 2. Line graphs of the total scores of the outcome variables from baseline to T4 (12months). Vertical bars represent the 95% CI of the mean.

The SCP-A was effective in decreasing women's unmet needs after six months and decreasing their fear of recurrence after 12 months. The change in QoL was greater after 12 months in the SCP-A. However, there was no evidence of an intervention effect on symptom distress, anxiety, and depression.

While there have been limited studies examining the long-term effects of web-based interventions, the findings of the current study are inconsistent with previous reports. Van den Beg and others (2105) [29] developed a web-based self-management intervention for early breast cancer survivor to improve psychological adjustment. The results revealed a short-term improvement in psychological distress in the 4th month and fear of recurrence in the 4th and 6th months. However, these effects did not persist in the 1 year follow-up. The short-term effect may have been due to the fact that the website was only available to women for 4 months in Van den Beg's study. Willems et al. (2017) also developed a website with 7 self-management modules to increase cancer survivors' quality of life. The study results showed a significant effect on depression, the social and emotional domains of quality of life, and fear of recurrence in the 6th month. However, the effect did not remain at the 1 year follow-up [30]. In Willem's study, nearly one third of the women used only one module with over 80% of participants not using any materials after 18 weeks [31]. In the current study, the SCP-A continued to provide new information during the follow-up period, which may be responsible for the difference in the findings. Women in the intervention group also received a reminder message from the app after new information was released. The effect may have persisted because women were encouraged to access the website throughout the study period.

The only outcome measure to significantly change at 3 month was unmet needs Other studies have reported that psychological outcomes such as anxiety, distress, fear of recurrence, and quality of life improved significantly in the 3rd or 4th month after a website intervention [29,32]. However, such studies involved more intensive online programing that provided assessments and information, but also assigned the women activities to complete. As a result, effects were detected during the short-term period. A recent study [33] provided an information-based website to decrease distress for breast cancer survivors that reported no effect on unmet needs. However, a limited level of engagement with the website, where the majority of the women accessed the website only one time, could explain the lack of effect. Depression and anxiety were not influenced by SCP-A engagement in this study. The low level of depression and anxiety in our sample may have made any change undetectable.

A significant decrease in fear of recurrence at the 12-month follow-up is inconsistent with previous findings [29]. Even though the SCP-A intervention did not require the completion of activities, one module in the intervention suggested methods to reduce fear of recurrence. This finding supports a recent study testing a fear of recurrence model [34]. Because symptoms or information can trigger fear, providing detailed information that assists women to distinguish significant from insignificant symptoms can offer reassurance.

The intervention group reported more symptoms compared to the control group at T1, T2, & T3 with level of symptom distress unchanged. These findings are similar to previous studies that showed patients receiving SCP reported more concern about their illness and therefore reporting more symptoms [9,35]. In addition, a message reminding the intervention group to monitor their symptoms may have raised their symptom awareness.

While both groups reported improved QoL after 1 year, the intervention group showed a greater change. These findings are similar to those found by Nicolaije, et al. (2015). Fewer unmet needs and less fear of recurrence may have contributed to the better QoL of the intervention group at 1 year.

The strengths of the current study include having a long-term follow-up with validated measurements, and a lower attrition rate as compared to previous reports. However, limitations include the frequency of women in control group who used other resources for information, which may have led to effect underestimation. Women with an iPhone (non-Android) randomized to the intervention group were excluded. Even though mixed method analysis was used to correct for differences at baseline, the groups were not equal, and thus, the results should be interpreted with caution.

4.2. Conclusion

An information website application for women with breast cancer can decrease their unmet needs, and fear of recurrence. The quality of life of breast cancer women can be improved with short and long-term use of structured website information.

4.3. Practice implication

Web-based information that provides survivorship care plans for women with breast cancer survivors is beneficial. Frequent reminder messages and frequent information updates promote website usage and increase the positive effects of interventions. Future research attempting to understand SCP-A usage and satisfaction will lead to improvements in the educational materials. Further study investigating the fear of recurrence in breast cancer survivors is needed. Moderators examining the effects of age, education level, and treatment type [30] could also lead to a deeper understanding of which participants would benefit more from an SCP-A intervention.

Ethical approval

Ethical approval was given by a committee from National Cheng Kung University Hospital (Taiwan) (IRB number B-ER-104-397). All procedures performed involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. The authors have full control of all primary data, and they agree to allow the journal to review their data if requested.

Informed consent

Informed consent was obtained from all individual participants included in the study.

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Declaration of Competing Interest

The authors declared that they have no conflict of interest.

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Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at doi:https://doi.org/10.1016/j.pec.2019.09.012.

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