The Effectiveness of an App-Based Breast Cancer e-Program in China: A Multi-Center Randomized Controlled Trial

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Purpose:

Women with breast cancer undergoing chemotherapy have frequently reported unmet supportive care needs (Au et al., 2013). Easily accessible and innovative support is lacking. With advanced technology, mobile applications (apps) provide an easily accessible platform to reach the large group of women with breast cancer (Bender, Yue, To, Deacken, & Jadad, 2013). However, there remains a paucity of randomized controlled trials (RCTs) to evaluate the effectiveness of app-based programs targeting women with breast cancer undergoing chemotherapy (Zhu, Ebert, & Chan, 2017). Furthermore, women’s usage of eHealth interventions and their relationship with effectiveness has rarely been reported in trials (Berry, Blonquist, Patel, Halpenny, & McReynolds, 2015).

The purpose of this trial was to determine the efficacy of an app-based Breast Cancer e-Support (BCS) program regarding self-efficacy, social support, symptom distress (symptom severity and symptom interference), Quality of Life (QoL), anxiety and depression. Secondary objectives included exploring the association between the BCS usage data and women’s health outcomes.

Methods:

A multi-center, single-blinded, randomized controlled trial was conducted in China. Bandura’s self-efficacy theory and the social exchange theory guided the development of the BCS program, which has four components: 1) a Learning forum; 2) a Discussion forum; 3) an Ask-the-Expert forum; and 4) a Personal Stories forum. Taping into different forum enable women to find knowledge, watch encouraging stories, and communicate with one another and health care professionals (Zhu, Ebert, Xue, Shen, & Chan, 2016). Women with breast cancer (n=114), who were commencing chemotherapy and were able to use mobile phone to access the internet, were recruited from two university-affiliated hospitals. Women were randomized into the intervention group who received routine care plus 12-week access to the BCS program or control group who received routine care. Health outcomes were measured at baseline, 3 months, and 6 months.

Results:

BCS participants showed significant improvement at 3 months regarding self-efficacy, symptom interference, and QoL (all P<.05) but not regarding social support, symptom severity, anxiety and depression compared to control participants. These beneficial effects were not sustained 12 weeks after intervention.

At baseline, the usage duration of the BCS program was positively correlated with self-efficacy (r=.439, P=.001) and quality of life (r=.313, P=.020), while inversely related to symptom severity (r= -.297, P=.027). At 3 months, the usage duration of whole program were positively related to self-efficacy (r=.290, P=.032), social support (r=.320, P=.017), and QoL (r=.273, P=.044). At 6 months, the usage
duration of the whole program was correlated with self-efficacy ($r=.329$, $P=.014$), while inversely correlated with anxiety ($r=-.300$, $P=.026$).

**Conclusion:**

The BCS program significantly improved the women's self-efficacy and QoL at 3 months. Additionally, the usage duration of the whole BCS program was positively related to self-efficacy and QoL at 3 months. Consistent with prior research (Shorey, Chan, Chong, & He, 2015; Zhang et al., 2014), we demonstrated that the self-efficacy theory and social exchange theory are usable and effective in guiding the development of the BCS program to improve the women’s self-efficacy and QoL.

This study achieved a significant group difference in symptom distress only for the subscale of symptom interference, not for the subscale of symptom severity, at 3 months. The knowledge provided and the interaction within the BCS program may modify the women's interpretation of the extent to which symptoms interfered with their daily lives. Regarding symptom severity, at baseline, higher levels of symptom severity were inversely correlated with usage duration of the BCS program. Some women might have experienced high levels of symptoms such as pain or fatigue that hindered their engagement, potentially diluting the results. Future app-based studies might involve the caregiver using the app when the patients are experiencing severe symptoms.

Our study found no significant difference in social support between the two groups at 3 months. However, in the intervention group, the women's perception of social support increased in relation to the usage duration with the BCS program at 3 months. The lack of significant result on social support may be due to insufficient engagement of the BCS program. Process evaluation are needed to explore the challenges to engagement and difference corresponding strategies should be addressed to promote the engagement.

Additionally, the study found that the BCS program did not significantly reduce the BCS participants' anxiety and depression at 3 months. Access to a wide variety of information materials related to breast cancer and chemotherapy may not relieve the women's anxiety and depression (Loiselle, Edgar, Batist, Lu, & Lauzier, 2010). To date, literature has inconsistent findings regarding the effects of eHealth on anxiety and depression for cancer patients (Slev et al., 2016). Further studies must be conducted to obtain more conclusive findings.

This study found no long-term effects for women using the BCS program at 6 months. This may be because women could access the BCS program for 12 weeks only. However, the physical and psychosocial symptoms may persist for 12 months or even longer after the completion of the chemotherapy (Stanton, 2012). Thus, future study should allow participants to retain access to the BCS program longer to achieve long-term effect.

This research is one of the first RCTs to explore the effect of an app-based intervention for women with breast cancer undergoing chemotherapy. The BCS program demonstrated its potential to support women during chemotherapy. Our study has global significance because mobile apps are being increasingly utilized as supplementary interventions for individuals when the feasibility of face-to-face interventions are challenged by physical limitations or geographic distance. The knowledge generated from the study can be used to develop guidelines for future healthcare app development.

**Title:**
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**Keywords:**
Breast cancer, Chemotherapy and Mobile application
References:


Abstract Summary:
This is the first study to demonstrate the app effectiveness with multi-center randomized controlled trials for women with breast cancer undergoing chemotherapy in China. Our study has global significance because mobile apps are being increasingly utilized as supplementary interventions for individuals when it is not feasible to provide face-to-face interventions.

Content Outline:
1. Introduction

A. Breast cancer in the world and in China
B. Integrative review on internet-based intervention for women with breast cancer undergoing treatment. Knowledge gaps: there remains a paucity of randomized controlled trials to evaluate the effectiveness of app-based programs targeting women with breast cancer undergoing chemotherapy.

2. Methods

A. aims of the study

   a. To determine the efficacy of a mobile application (app) for a Breast Cancer e-Support (BCS) program to address women's self-efficacy, social support, symptom distress, Quality of Life (QoL), and anxiety and depression.

   b. To explore the association between women's health outcomes and the BCS usage data.

B. Theoretical framework

   a. Bandura's self-efficacy theory

   b. Social exchange theory

C. Development process

   a. Website (breastcanceresupport.xmu.edu.cn) demonstration.

   b. Four components: Learning forum, Discussion forum, Ask-the-expert forum, Your story forum

   c. Video demonstration

D. Clinical randomized controlled trial

   a. Study venues: Zhongshan hospital, Hunan Cancer Hospital

   b. Participants: Women with breast cancer who were commencing chemotherapy and who can access internet via mobile phone

   c. Data analysis: Intention-to-treat analysis, MAMCOVA, The Spearman's rank-order correlation

3. Results

A. CONSORT Flowchat

B. Demographic and clinical variables of participants from both groups at baseline

C. Effect of BCS program

   a. BCS participants showed significant improvement at 3 months regarding self-efficacy, symptom interference, and QoL (all p<.05), but not regarding social support, symptom severity, anxiety and depression compared to control participants.

   b. These beneficial effects were not sustained 12 weeks after intervention.
D. Usage data of BCS program for women in the intervention group

E. The association of usage data of BCS program and health outcomes.
   a. baseline: self-efficacy, QoL → (+) the usage duration of the whole BCS program
      symptom severity → (-) the usage duration of the whole BCS program
   b. at 3 months: self-efficacy, social support, QoL→ (+) the usage duration of the whole BCS program
   c. at 6 months: self-efficacy → (+) the usage duration of the whole BCS program
      anxiety→ (-) the usage duration of the whole BCS program

4. Discussion

A. Beneficial effect on self-efficacy, QoL at 3 months

B. Beneficial on subscale of symptom interference of symptom distress, but not on subscale of symptom severity

C. No significant difference between two groups on social support. Explain and explore strategies

D. No significant effect on anxiety and depression. Explain

E. No long-term effect. Explain and suggestions for future research

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