DEVELOPMENT OF A SELF-MANAGEMENT PROGRAM IN PATIENTS WITH BREAST CANCER UNDERGOING CHEMOTHERAPY: DESIGN OF A RANDOMIZED CONTROLLED TRIAL

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Background: Breast cancer (BC) is the top leading cause of women's cancer, an estimated 28 women are diagnosed with BC and 5 women died due to BC every day in Taiwan. Although there is a growing number of BC women, there is a very great effect in treatment of BC. Especially, chemotherapy (CT) as adjuvant therapy which is the most prevalent method used to treat BC. However, a growing number of people suffer from the side effects of CT, which would be deeply affecting patient's quality of life. There is hence an urgent need of careful intervention program design in order to enhance patients' health-related outcomes in BC patients during the CT. Self-management (SM) is worldwide reported as an effective approach to utilize for those with chronic disease. However, there are still many questions that remain unanswered in regards to incorporation instant messaging (IM) by mobile and internet, SM and BC patients. Therefore, it seemed appropriate to develop an IM SM (IMSM) program managing day-to-day health behavior via IM, which designed for implementing treatment program management, real-time monitoring and support, and disease health knowledge to patient and help them achieve SM. It is hypothesized that an intensity IMSM program at this time will has clinical benefits for BC patients to deal with CT.
Methods: This quantitative research will be divided into two phases in three years. The Phase I will develop IMSM intervention and carry out the pilot study. Then, the psychometric testing of the instruments will be also completed before the pilot study. In the Phase II, an experimental design will be used to examine the effectiveness of an IMSM intervention. In this randomized controlled trial of 12 months duration, total 136 patients undergoing CT will be recruited while the participant at the clinic of a hospital. The experimental group (N=68) will receive IMSM intervention added to the clinical routine care, and the control group (N=68) will receive with the clinical routine care only. The IMSM intervention is developed based on Bundura's self-efficacy theory, which provides four sources of information for SM. The strategies of the IMSM consist of real-time supportive, appraisal, goal setting and self-monitoring of exercise and diet for CT and symptom management. The "symptom management" strategy in this study will be focused on early sign of side effects from CT. In order to examine the effects of IMSM intervention, data will be collected with 5 time points by nine health-related outcomes. The outcome variables will be body weight, body mass index, six-minute walk test, physical function, self-efficacy, anxiety and depression, symptoms, quality of life and the use of health services. Assessments will be conducted at baseline (pre-CT) and at 1, 3, 6 and 9 months following the first cycle of CT. Outcome measures of this study will be analyzed using descriptive and inferential statistics with the generalized estimating equations (GEE) analysis.
Conclusion: The findings of this study would generate an effective IMSM model for health professional to facilitate BC patients undergoing CT the development of self-care capability and improvement of health-related outcomes.

Index Terms - Breast cancer, self-management, self-efficacy, chemotherapy, instant messaging, randomized controlled trial