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## A home-based, nurse-led health program for postoperative patients with early-stage cervical cancer: A randomized controlled trial



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#### ABSTRACT

*Purpose*: To investigate the effect of a home-based, nurse-led health program on quality of life and family function for postoperative patients with early-stage cervical cancer.

Method: 226 cervical cancer patients, from two hospitals between December 2012 and April 2014, were randomly divided into intervention and control groups. Patients in the intervention group received an individual home-based, nurse-led health program (family-care team provision, physiological rehabilitation, emotion-release management, informal social support system, and follow-up monitoring), in addition to conventional nursing education. Patients in the control group only received conventional nursing education. The Functional Assessment Cancer Therapy-Cervix, Female Sexual Function Index, and the Family Adaptability and Cohesion Scale were used for assessment before and after the intervention.

Results: After the intervention, significant improvements were found for the quality of life total scores  $(t=-7.650,\ p=0.000)$ , sexual function scores  $(t=-6.465,\ p=0.000)$ , cohesion scores  $(t=-8.417,\ p=0.001)$  and adaptability scores  $(t=-10.735,\ p=0.000)$  in the intervention group. Moreover, proportions of family types were also improved  $(\chi 2=17.77,\ p=0.000)$ . However, for the control group, no significant differences were found except for a decrease in sexual function scores  $(t=-4.035,\ p=0.000)$ . Significant differences in change scores between groups were also found for quality of life  $(F=41.980,\ p=0.000)$ , Sexual function  $(F=37.380,\ p=0.000)$ , cohesion  $(F=15.268,\ p=0.000)$  and adaptability  $(F=16.998,\ p=0.000)$ .

*Conclusion:* A home-based, nurse-led health promotion program improves the quality of life, sexual function and family function in postoperative patients with early-stage cervical cancer.

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#### 1. Introduction

Cervical cancer (CC) is the most common malignant tumor of the female reproductive system. With improved therapies and early screening technology, CC is being detected with increasing incidence, and the age of onset has become younger. Peak incidence is now estimated to be in women 40 years of age (Belot et al., 2008). According to the NCCN guidelines, surgery should be the primary

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treatment for early-stage CC (IA to IIA), leading to 5-year relative survival rates ranging from 63% to 93% (Edge and Compton, 2010; Howlader et al., 2014). Moreover, localized CC is a curable disease, with a 5-year relative survival of 91—93% (Horner et al., 2009; Jemal et al., 2008; Siegel et al., 2012). In spite of better prospects for cure, treatment-associated side-effects continue to plague patients for many years. Outside of the physical side-effects, such as sexual function and childbearing, menopausal, urologic, and gastrointestinal symptoms, anxiety and depression are the most prevalent psychological symptoms perceived by cancer patients (Takahashi et al., 2008).

Quality of life (QOL) is the perceived quality of an individual's daily life, that is, an assessment of their well-being including all emotional, social, and physical aspects of the individual's life. It is

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an assessment of how the individual's well-being may be affected over time by a disease, disability, or disorder (Bottomley, 2002). It has been utilized as a primary outcome measure. Treatment-related side-effects, including physical, psychosocial, and sexual well-being, have been associated with QOL (Vistad et al., 2006). Accordingly, further research focusing on quality of life in postoperative patients, and identification of a better intervention to improve their health and well-being, is of great importance. In addition to quality of life, family function and sexual function were also serious problems for cancer survivors. Family function has been associated with levels of family distress, depression and anxiety. Results from multilevel models indicated that anxiety and depression are the most prevalent psychological symptoms perceived by cancer patients (Frick et al., 2007; Takahashi et al., 2008), which lead to a worse family function. It was reported that patients who received cervical cancer surgery have sexual problems including lack of interest in sex, dyspareunia, and especially anxiety about sexual performance (Grumann et al., 2001; Jensen et al., 2004; Park et al., 2007).

Home-based nursing intervention (HBNI) is a new nursing program that extends nursing intervention from the hospital to the home in China. HBNI, is carried out by nurses and other health-care professionals (e.g. psychologists and physiotherapists), with the aim to improve health and functional status, and may promote quality of life for postoperative patients. Different from home care. HBNI emphasize the important role of nursing team and nurse-led intervention. That is to say, effective execution of HBNI depends on a family nursing team, targeted exercises, and participation of both the patient and patient families. Previous studies have suggested the importance of transitional care strategies, from hospital to home, for HBNI (Rennke and Ranji, 2015; Tappenden et al., 2012). Recently, randomized controlled trials have used HBNI for different patients. In a study involving patients with colorectal and breast cancer, participants were randomly assigned to receive either a home care program or standard care for 18 weeks. Following the intervention, the authors found that a home care nursing program could assist patients in managing adverse effects (i.e. anxiety, depression, and quality of life) more effectively than standard care (Molassiotis et al., 2009). Additionally, exploration of the potential impact of a nurse-led telephone intervention on colorectal cancer patients concluded that a nurse-led telephone intervention benefits cancer survivors and is cost-effective (Craven et al., 2013). Research also suggests that specific exercises at home are effective interventions for older patients (Steadman et al., 2003) or patients with chronic obstructive pulmonary disease (COPD) (Neves et al., 2014; Ng et al., 2014; Wong et al., 2012). Encouragingly, a prior study examines the physical and psychological benefits afforded by a 7-week voga program for breast cancer survivors (Nicole Culos-Reed et al., 2006). Recently, randomized controlled trial (Harder et al., 2015) and meta-analysis (Buffart et al., 2012) also confirm the effects of yoga on physical or/and psychosocial outcomes in cancer patients and survivors. Taken together, it seemed possible that yoga have a beneficial impact on cancer survivors. All home nursing care research involves special nursing interventions according the characteristics of the disease. However, to our knowledge, no studies have applied HBNI in postoperative patients with early-stage cervical cancer. In this study, we introduced HBNI in postoperative patients with earlystage cervical cancer, drafted a home-based, nurse-led health promotion (NLHP-HB) program, and sought to evaluate the effectiveness of the NLHP-HB program (compared with conventional nursing care) on quality of life, sexual function and family function.

#### 2. Methods

#### 2.1. Participants and groups

This study was approved by the hospital and university Ethics Committee. All patients signed informed consent forms after the authors explained the purpose of the study. A randomized, controlled trial was used. Random assignment was carried out using simple random methods that were designed and processed by statisticians. Random numbers were obtained from random number tables given in a statistical book. Every random number was divided by group number to generate remainders. Remainders were used to decide the group to which a patient would be assigned. All patients were recruited from two local hospitals. The 244 eligible patients included were diagnosed from December 2012 to April 2014. Among them, 18 patients were excluded because of missing contact information. The remaining 226 patients were randomly divided into the intervention group (n = 119) or control group (n = 107). The detailed eligibility criteria were as follows:

- Diagnosed with stage IA to IIA cervical cancer according to the International Federation of Gynecology and Obstetrics (FIGO) standard.
- 2. Did not have any radiotherapy and/or chemotherapy,
- 3. Patients received a first operation, but did not display recurrent cervical cancer.
- 4. Did not have severe cardiovascular disease, acute or chronic pulmonary disease, diabetes, or mobility limitations.

#### 2.2. Protocol

Patients in the control group only received conventional nursing care, whereas those in the intervention group additionally received NLHP-HB care. The intervention took 6 months. All patients filled out a pre-intervention evaluation questionnaire within 7 days post-surgery. A post-intervention evaluation was conducted 6 months after NLHP-HB care in a similar manner for patients in both groups.

#### 2.2.1. Conventional nursing care

- Drug education: information about the drug and its adverse effects was provided by the clinicians and accompanied by written information.
- 2. Nutrition nursing: a nutrition-balanced diet was recommended to include fresh vegetables and fruits, and animal protein.
- 3. Health education about cervical cancer: characteristics of the cancer and how to care for and strengthen the reproductive tract were explained.
- 4. Follow-up education: patients were given the telephone number for the hospital's 24-h emergency hotline. Conventional follow-up in the outpatient department was finished.

#### 2.2.2. NLHP-HB program

- Establishment of a family care team: a family care team was established consisting of specialist nurses, gynecological doctors, physiotherapists, psychological consultants, dietitians and physical therapists. A specialist nurse served as the leader and was responsible for nursing education, promoting the program, collecting scales, and carrying out the follow-up. Other team members provided consultation and advice based on their respective expertise.
- Physiological rehabilitation: standard Kegel exercises, for pelvic floor muscle training (PFMT), were introduced specifically for this program. PFMT began by emptying the bladder, and then

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