



Effects of nurse-led home-based exercise & cognitive behavioral therapy on reducing cancer-related fatigue in patients with ovarian cancer during and after chemotherapy: A randomized controlled trial

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ABSTRACT

Background: High levels of fatigue have been documented in ovarian cancer patients. However, increased levels of fatigue are positively associated with a high risk of sleep disturbance and depression.

Objective: To investigate the feasibility of a nurse-led home-based exercise and cognitive behavioral therapy (E & CBT) for ovarian cancer adults with cancer-related fatigue on outcomes of fatigue, plus other secondary outcomes (sleep disturbance and depression), either during or after completion of primary cancer treatment.

Design: Randomized, single-blind control trial.

Settings: Gynaecologic oncology department of the First Hospital of Jilin University in China.

Participants: 72 eligible women who recently had surgery and completed their first cycle of adjuvant chemotherapy were randomly assigned to two groups.

Intervention: The experimental group received exercise and cognitive behavioral therapy. Five nurses with nursing master degree were trained to deliver this intervention. Patients received online interventions each week in the patient's place of residence or in the nurse-led clinic, as requested. Home visits, coupled with telephone-based motivational interviews twice a week were available with the permission of the participants. comparison group participants received services as usual.

Measurements: The primary outcome was measured by the Chinese version of the Piper Fatigue Scale that has 4 subscales (Behavior, Affect, Sensory, and Cognition). Secondary outcomes were measured using the Self-Rating Depression Scale and the Pittsburgh Sleep Quality Index questionnaire. Repeated-measure ANOVA was used to examine the effectiveness of this intervention in reducing fatigue, depression, and improving sleep quality.

Results: For baseline comparisons, no significant differences were found between the two groups. After the interventions, total fatigue scores were significantly reduced from T1 to T2, to T3 in the experimental group (4.37, 4.24, 3.90), respectively. The comparison group showed almost no change in total fatigue score over time. In the repeated measures ANOVA, the differences of behavioral fatigue score ($F = 11.647$, $p = 0.001$) and cognitive fatigue score ($F = 5.741$, $p = 0.019$) were statistically significant for the group by time interaction. After the interventions, the experimental group participants demonstrated significantly lower symptoms of depression compared with the comparison group (T2: $p = 0.001$ and T3: $p < 0.001$). Sleep duration, sleep dysfunction, daytime dysfunction as well as total sleep quality significantly improved.

Conclusion: Nurse-delivered home-based E & CBT have measurable benefits in helping women with ovarian cancer to decrease cancer-related fatigue, depressive symptoms, and improving their quality of sleep.

What is already known about the topic?

- Patients can experience fatigue during and after chemotherapy, and are often under-diagnosed and under-treated.
- CRF management includes cognitive behavioral and exercise

interventions. However, no studies found compared the effects of trained nurse home-based delivery of these two strategies among ovarian cancer patients with fatigue.

What this paper adds

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- This result provides evidence that a nurse-delivered home-based exercise and cognitive behavioral therapy can be beneficial for the management of cancer-related fatigue, depressive symptoms, and improved quality of sleep.

1. Introduction

Cancer-related fatigue (CRF) is a widespread problem experienced by oncology patients (Minton et al., 2013) with multiple symptoms of distress. It has an ubiquitous influence affecting oncology patients and survivors, which can persist for many years after curative treatment has ended (Horneber et al., 2012). According to the National Comprehensive Cancer Network (Berger et al., 2015), CRF is defined as an overwhelming persistent subjective sense of tiredness or exhaustion (physically, emotionally, and/or cognitive), or a sensation of weakness or tiredness related to cancer or cancer following treatment (Williams et al., 2016). Advances in cancer treatment have led to a rise in the range of severity and frequency of CRF (Spichiger et al., 2012). However, CRF is often under-treated and under-diagnosed due to the different methods of assessment. The prevalence of CRF varies across studies: approximately 80% to 96% of cancer patients undergoing chemotherapy report complaints of fatigue and 60%–93% of patients with cancer receiving radiotherapy (Horneber et al., 2012; Spichiger et al., 2012; Tian et al., 2016a, 2016b). High levels of severe fatigue have been documented in ovarian cancer patients (Anderson and Hacker, 2008; Clevenger et al., 2012; Shinde et al., 2015). CRF is a highly reported “pre-diagnostic symptom” occurring prior to ovarian cancer (Goff et al., 2004, 2000). In addition, numerous studies indicated that increased levels of fatigue are positively associated with a high risk of sleep disturbance and depression (Ancoli-Israel et al., 2014; Holzner et al., 2003; Matulonis et al., 2008).

Currently CRF treatment options can be classified into 1) pharmacologic (Qu et al., 2015), e.g.: psychostimulants, which need clinical trials to confirm the safety, and 2) non-pharmacologic (Modlinska et al., 2014; Pearson et al., 2016) e.g.: exercise and cognitive behavioral therapy (CBT). These two effective strategies are recommended to decrease CRF.

Exercise treatment is an accessible, cost-effective activity used in reversing CRF (Tomlinson et al., 2014). A recent meta-analysis (Tian et al., 2016a, 2016b) of RCTs has determined the significant effectiveness of exercise on reducing CRF (pooled standardized mean difference (SMD) was -0.22 , revealing a large clinical effect). Previous studies (Cramp and Byron-Daniel, 2012; Goedendorp et al., 2014; McMillan and Newhouse, 2011; Moonsammy et al., 2013; Tomlinson et al., 2014; Zou et al., 2014) confirmed that exercise and CBT interventions were able to reduce CRF and improve mood, as well as sleep functioning in other cancer populations. The exercise program coordinated with CBT (i.e., fatigue management and exercise training) in this study was based on effective components designed for decreasing CRF from previous studies (Moonsammy et al., 2013). Nurses play a crucial role in assuring patient’s health (who undergo multiple regimens of chemotherapy), including improved physical and mental well-being (McGowan, 2016). Therefore, this exercise and CBT programs were combined with nurse-led interventions.

A wide range of well-designed interventions were conducted during cancer treatment. Limited resources were available, however, to evaluate the effectiveness of home-based exercise and CBT training during and after cancer treatment to decrease the adverse effects of CRF. Studies by Hoffman et al. and by Chen et al., found that home-based exercise interventions contributed to the reduction of fatigue levels for patients with lung cancer (Chen et al., 2015; Hoffman et al., 2013). The effects of two home-based interventions (exercise and CBT combined) among ovarian patients is largely unexplored. Therefore, the primary purpose of this pilot study was to investigate the feasibility of a nurse-led home-based E & CBT for adults with ovarian cancer and to study the effects on both primary (CRF) and secondary outcomes (sleep

disturbance and depression). Secondary purposes were to test the severity of CRF with the timing of intervention, either during or after completion of the primary cancer treatments.

2. Methods

2.1. Study design

This study was conducted between November 2014 and November 2015. It was designed as a single-center randomized controlled trial with two parallel groups.

2.2. Eligibility criteria

2.2.1. Inclusion criteria

Patients were recruited for the study if they: (a) were female between the ages of 18 and 80; (b) had a confirmed diagnosis of ovarian cancer and had completed primary treatment and decided to receive chemotherapy treatment; (c) were experiencing moderate (4–6) to severe (7–10) levels of fatigue (National Comprehensive Cancer Network, 2011); (d) were fluent in Mandarin Chinese; (e) had no contraindications to exercise; and (f) had and were willing to access to the internet.

2.2.2. Exclusion criteria

Reasons for exclusion included: physicians confirmed the health conditions that prevented patients from engaging in this study through clinical assessment as well as physical examination; Patients with symptoms such as severe osteoporosis, severe paralysis, or previous spinal operations which made them too ill to performing strenuous exercise; Past history of cognitive disorders, mental conditions or major sleep disorders.

2.3. Setting and participants

Patients were recruited from the gynaecologic oncology department of the First Hospital of Jilin University in Chang Chun, Mainland China.

2.4. Measures

Eligible participants completed a questionnaire package, provided by nursing staff, at baseline (before their second chemotherapy treatment, T1), immediately after a 12-week intervention (before the sixth chemotherapy treatment, T2) and 3 months after intervention (approximately 3 months after the end of the sixth chemotherapy treatment, T3). Eligible participants were scheduled to complete assessments either at the clinic or in their homes. The first two (T1 and T2) assessments took place when the patients returned to the hospital for their hospitalized chemotherapy. The assessments were postponed when the 21-day chemotherapy cycle was delayed. The last assessments were performed in the participants’ homes. All participants provided written informed consent.

2.4.1. Baseline measures

Eligible patients were invited to participate in the baseline measurements. Patients completed the questionnaires themselves, and data was collected by a separate research nurse. Questionnaires included the following demographic information: participant’s age, educational level, family caregivers, marital status, and household income. Patient’s hospital information was also collected from patients’ clinical records. Relevant information included: cancer diagnosis, stage of disease, comorbidity conditions and treatments received.

2.4.2. Primary outcome measures

CRF was measured by the Mandarin Chinese version of the Piper Fatigue Scale (PFS). The scale (So et al., 2003) consists of a 22-item

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