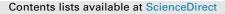
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A randomized controlled trial of qigong on fatigue and sleep quality for non-Hodgkin's lymphoma patients undergoing chemotherapy



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ABSTRACT

Purpose: This study aimed to evaluate the effects of Chan-Chuang qigong exercise in non-Hodgkin's lymphoma patients who were undergoing chemotherapy on fatigue intensity and sleep quality. *Methods:* The study was a single-centre, controlled randomized study. One hundred and eight subjects were randomly assigned to the qigong group (n = 54) or control group (n = 54). The qigong group received Chan-Chuang qigong exercise 20-min twice daily for 21 days in the course of the chemotherapy treatment, whereas the control group without special exercise intervention. Outcome measures included fatigue and sleep quality.

Results: After the three-week intervention, participants who were in the qigong group had lower fatigue intensity scores than those in the control group. The results of generalized estimating equations (GEE) analyses showed a significant group-by-time interaction effect in average fatigue, worse fatigue, and overall sleep quality (p < 0.001). The average fatigue, worse fatigue, and overall sleep quality significantly decreased over time in the qigong group.

Conclusions: Chan-Chuang qigong exercise could be regarded as an adjunct measure in clinical practice. This study cannot completely discount the possible influence of placebo effects, and more objective clinical outcome measures are needed to produce our findings with long-term follow-up in a randomized controlled study.

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1. Introduction

Non-Hodgkin's lymphoma is the sixth most common noncutaneous cancer in the United States (National Cancer Institute, 2012). With a main treatment of chemotherapy, patients with non-Hodgkin's lymphoma have a five-year survival rate of 68% (Horner et al., 2009). However, these non-Hodgkin's lymphoma survivors commonly encounter physical dysfunction, appetite loss, and loss of vitality according to a systematic review (Oerlemans et al., 2011). In addition, chemotherapy causes fatigue, sleep disturbance, and depressed mood in a cascade pattern. Prevalence rates for non-Hodgkin's lymphoma related fatigue are between 47% and 61% (Oerlemans et al., 2013; Wang et al., 2002). Sleep disturbance could worsen to fatigue, which in turn worsens to mood depression (Siefert, 2010). Interventions targeting symptoms early in the above cascade pattern may provide benefits across multiple symptoms (Jim et al., 2013).

Exercise is receiving increasing attention as a supportive therapy for patients with cancer and survivors. Non-Hodgkin's lymphoma survivors who adhere to public health exercise guidelines have exhibited clinically improved physical and mental health compared with those who did not exercise (Bellizzi et al., 2009). One study provided pateints with multiple myeloma a three-month exercise program during their treatment, and resulted in decreased fatigue disturbance and improvement of sleep quality (Coleman et al., 2003). The other study provided patients with haematological cancer exercised daily on a treadmill during hospitalization, and found improvement of fatigue level and psychologic distress (Dimeo et al., 2003). However, a randomized controlled trial evaluated the effect of aerobic exercise on sleep quality in lymphoma patients receiving chemotherapy or no treatment, and yielded no significantly improvement in sleep quality (Courneya et al., 2012). It is noted that no previous studies have examined the effect of gigong exercise on fatigue intensity and sleep quality for patients

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with non-Hodgkin's lymphoma.

Qigong exercise, a mind-body practice, uses physical activity and meditation to harmonise the body, mind, and spirit. As a crucial practice in traditional Chinese medicine, qigong is used to prevent diseases and improve health and energy levels through regular practice (Lee et al., 2007). Qigong is a series of exercises including breathing, meditation, intention, and rhythmic movements that can be learned by people of any age and physical condition (Lee et al., 2003). Chan-Chuang qigong, a qigong discipline, strengthens the internal qi (vital energy) of the human body and preserves health; moreover, it has few side effects and has practical and medicinal applications (Yeh et al., 2006; Yi, 1989). Standing in relaxed posture, circling the arms akin to hugging a tree trunk, breathing naturally, and maintaining balance is central to Chan-Chaung qigong (Yeh et al., 2006). Non-Hodgkin's lymphoma patients who have undergone chemotherapy are extremely fatigued and weak, and cannot engage in strenuous gigong. Chan-Chuang qigong can be easily learned by beginners and thus is a favorable form of physiotherapy for restoring the strength and health of patients with cancer (Yeh et al., 2006).

Several previous studies have indicated that qigong offers therapeutic benefits for patient with cancer, such as amelioration of symptoms and psychological distress (Lee et al., 2006). Qigong decreases fatigue (Kim and Kim, 2002), leucopenia (Yeh et al., 2006), and depression (Overcash et al., 2013) and improves quality of life, mood, and inflammation (Oh et al., 2008, 2010). However, a systematic review by Lee et al. (2007) indicated that rigorous clinical trials have failed to support the effectiveness of qigong in cancer care. Therefore, this study aimed to evaluate the effects of Chan-Chuang qigong exercise in non-Hodgkin's lymphoma patients who were undergoing chemotherapy on fatigue intensity and sleep quality. We investigated the hypotheses that the Chan-Chuang qigong exercise program significantly reduces fatigue intensity, and significantly improves sleep quality.

2. Methods

2.1. Study design and study sample

This study was a single-centre, randomized controlled trial. Ethics approval was obtained from the ethics review committee of the administering institutes. Participants were recruited from the oncology ward of a 2900-bed medical centre in northern Taiwan. The inclusion criteria were as follows: (1) at least 18 years of age and with a physician-confirmed diagnosis of non-Hodgkin's lymphoma; (2) prepared for the first course of chemotherapy with cyclophosphamide, vincristine, and prednisolone combined with rituximab; (3) without serious mental or cognitive impairment; and (4) considered by their medical oncologist to receive gigong intervention. Patients were excluded from the study if they had any following condition: (1) diagnosis of a major medical disease, such as uncontrolled arrhythmia, hypertension, unstable angina, severe respiratory disease, acute infection, multiple myeloma, bone metastasis, psychiatric disorders; (2) medical contraindications for exercise (e.g., orthopaedic problems and neurologic or musculoskeletal disturbances); or (3) already practicing gigong or other exercise training programs.

To determine a required sample size, G*Power software, version 3.1, was applied in this study (Faul et al., 2007). We based on an effect-size of 0.36 on a study by Larkey et al. (2014). Data were analysed using a repeated-measures test for between-group differences. A sample size was estimated at least 32 subjects per group at an alpha of 0.05 and a power $(1-\beta)$ of 0.90. We eventually recruited the total sample of 108 participants and then fulfilled the random assignment.

After completing informed consent and baseline measures, the participants were randomly assigned to the Chan-Chuang qigong (intervention) group and the routine care (control) group by a computer program that randomly ordered blocks of four participants; numbered, sealed, opaque envelopes were placed outside the study site. Blinding participants and researchers to the group assignment was not possible. To prevent possible bias, the study personnel involved in the recruitment did not have access to the randomisation lists. Participants were withdrawn on request if adverse effects caused by Chan-Chuang qigong were observed during assessments. Fig. 1 shows the flowchart of the research design and allocation of the participants.

2.2. Intervention

Guidance booklets, a modified version of the manual of Chan-Chuang qigong (Yeh et al., 2006) approved by two qualified gigong practitioners (ML and HH), was issued to the participants in the qigong group. The booklet focused on improving the physical function of non-Hodgkin's lymphoma patients and on alleviating their emotions and stress. It included a nursing guide for use during hospital stay and a telephone number for weekly contact after discharge. The booklet mainly contained an introduction to gigong, descriptions and photographs of qigong procedures, preparation guidelines and precautions, expected physical effects from practice, daily life monitoring guidelines, an attendance sheet, and a confirmation sheet. The research nurse, who was well-trained by the two gigong practitioners, followed the Chan-Chuang gigong protocol and individually trained the participants. The preparation of the intervention was conducted when the participants hospitalised for receiving the two-day treatment in the first cycle of chemotherapy treatment. The participants practised Chan-Chuang gigong until the research nurse was satisfied with the accuracy of their exercise movements and updated their confirmation sheet. In addition, the attendance checklist was used to ensure their daily participation and exercise duration.

After discharge from the hospital, the research nurse documented participants' adherence to the exercise regimen through weekly telephone contact. Although Chan-Chuang qigong is safe, with very low chance of developing adverse effects, the participants were taught to monitor and record adverse events in each gigong practice. To prevent potentially negative effects of the exercise on the participants' appetite and digestion, practising Chan-Chuang gigong was forbidden 30 min before and after meals. Any indoor or outdoor site with sunlight and fresh air was suitable. Participants were instructed to warm up for five minutes and practise for at least 15 min but not more than one hour in a single session (Yeh et al., 2006). They were asked to stop practising if they experienced discomfort or intense physical exhaustion. All signs of adverse events before, during, or after each session was also recorded. Two to three (but not more than five) daily sessions, equally spaced out, were recommended. Exercise compliance was defined as a proportion (%) of the number of practise sessions attempted to that scheduled. Chan-Chuang gigong did not cause side effects or induce additional physical stress in the participants in this study.

2.3. Instruments

2.3.1. Demographic and medical characteristics

Participants' demographic and medical characteristics, namely age, sex, highest education level, marital status, religion, employment status, cancer stage at diagnosis, and participant performance were recorded. Participant performance was measured by the Eastern Cooperative Oncology Group Performance Status (ECOG- Download English Version:

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