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Effect of acupuncture on patients with cancer-related fatigue during chemotherapy

Submission date 26/11/2014	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 24/03/2015	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 24/03/2015	**Condition category** Signs and Symptoms	[ ] Individual participant data [ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Adverse reaction is a key factor determining whether cancer patients can receive chemotherapy. It is also one of the main reasons for treatment failure. Fatigue is the most common symptom experienced by patients during chemotherapy. Fatigue is under-reported and often not screened for, partly because of a lack of helpful treatments. Many studies have investigated the benefits and success of acupuncture in easing symptoms for fatigue. Thus, the purpose of this study is to assess the effect of acupuncture on patients with cancer-related fatigue during chemotherapy.

Who can participate?
Patients with breast cancer or lung cancer who have at least two cycles of chemotherapy planned during the study program.

What does the study involve?
Participants are randomly allocated to one of two groups: the intervention group or the control group. Participants in the intervention group will receive acupuncture therapy three times a week for 3 weeks. Participants in the control group will receive shallow needle insertion that does not penetrate below the skin (minimal or superficial needling) at non-acupoints three times a week for 3 weeks. All the participants will complete some questionnaires at the start of the study and at the 3rd day, 7th day, 14th day and 21st day during the chemotherapy to find out about any changes in fatigue level, sleep, appetite and emotion. They will be followed up for a chemotherapy cycle (21 days) to assess long-term effectiveness.

What are the possible benefits and risks of participating?
All participants will receive free acupuncture treatment for nine times and a series of free examinations. The fatigue could be relieved. The results of this study may help to provide evidence that acupuncture is effective for managing cancer-related fatigue during chemotherapy. The risks of taking part are minimal. Acupuncture is a very safe treatment. The acupuncturist has an acupuncture license (Chinese medicine practitioner license) from the Ministry of Health of the People's Republic of China and takes an educational course to ensure that they strictly follow the study method and are familiar with conducting the study. Occasionally acupuncture can make people feel nauseous or faint, or can cause a temporary

increase in pain or a blood clot beneath the skin either during or after treatment. Participants are warned of these potential side-effects before consenting to have acupuncture.

Where is the study run from?
The study is run from three locations:
1. Beijing Hospital of Traditional Chinese Medicine affiliated to Capital Medical University, China
2. Beijing ShiJiTan Hospital affiliated to Capital Medical University, China
3. Beijing Friendship Hospital affiliated to Capital Medical University, China

When is the study starting and how long is it expected to run for?
From January 2014 to December 2016.

Who is funding the study?
Beijing Municipal Administration of Hospitals (China).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
XM201410

Study information

Scientific Title
Acupuncture for prevention and treatment of cancer-related fatigue during chemotherapy: a study protocol for a multicenter, randomized, controlled clinical trial

Study objectives

To assess the therapeutic effect of acupuncture on patients with cancer-related fatigue during chemotherapy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Beijing Hospital of Traditional Chinese Medicine Research Ethical Committee, 27/12/2014, ref: 2014BL-067

Study design
Multicenter randomized controlled interventional clinical trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Cancer-related fatigue

Interventions
The 112 eligible participants are randomly allocated to two different groups:
1. Participants in the intervention group will receive acupuncture therapy three times a week for 3 weeks.
2. Participants in the control group will receive minimal acupuncture therapy (shallow acupuncture at sham points) three times a week for 3 weeks.
All the participants will complete some questionnaires at the start of the study and at the 3rd day, 7th day, 14th day and 21st day during the chemotherapy to find out about any changes in fatigue level, sleep, appetite and emotion. They will be followed up for a chemotherapy cycle (21 days) to assess long-term effectiveness.

Intervention Type
Other

Primary outcome(s)
Piper Fatigue Scale-Chinese Version (PFS-CV), a multidimensional assessment tool for measuring the level of fatigue subjectively for patients with cancer. It will be assessed before chemotherapy, at the 3rd day, 7th day, 14th day and 21st day during the chemotherapy

Key secondary outcome(s))
1. TCM symptoms scale to evaluate TCM syndrome (deficiency of spleen qi and stomach qi)
2. TCM (traditional Chinese medicine) syndrome will be assessed before chemotherapy and at the 3rd day, 7th day, 14th day and 21st day during the chemotherapy

Completion date
31/12/2016

Eligibility

Key inclusion criteria
1. Patients with a definite pathologic diagnosis of breast cancer or lung cancer who had completed chemotherapy and/or radiotherapy at least 3 months, or never received chemotherapy and/or radiotherapy ever before
2. Aged 18-75
3. There are at least two cycles of chemotherapy planned during the study program
4. Eastern Cooperative Oncology Group (ECOG) performance status 0-2
5. Traditional Chinese Medicine (TCM) syndrome is differentiated as deficiency of spleen qi and stomach qi
6. Anticipated survival time is more than 6 months
7. All patients provided written informed consent before enrollment

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
75 years

Sex
All

Key exclusion criteria
1. Complicated with other serious heart, liver, kidney, immune and hematopoietic system diseases
2. Pregnant women or women who are breastfeeding
3. Patients who were on active treatment for anaemia (i.e., EPO or blood transfusions)
4. Patients who were receiving steroids to alleviate fatigue
5. Patients who had been diagnosed with depression, anxiety disorders, mental illness and cognitive disorders
6. Patients who had low platelet count or suffered from a bleeding disorder (e.g., haemophilia)
7. Complicated with sepsis or bacteremia
8. Patients who had lymphoedema at the area of the acupuncture points
9. Patients who are allergic to stainless steel needle or had needle phobia

Date of first enrolment
01/01/2014

Date of final enrolment
31/12/2016

Locations

Countries of recruitment
China

Study participating centre
Beijing Hospital of Traditional Chinese Medicine
No.23, Back Road of Gallery
Beijing
China
100010

Study participating centre
Beijing ShiJiTan Hospital
10 Tieyi Road
Haidian
Beijing
China

Study participating centre
Beijing Friendship Hospital
36 Yong'an Rd
Xicheng
Beijing
China

Sponsor information

Organisation
Beijing Municipal Administration of Hospitals

ROR
https://ror.org/04baakq55

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Beijing Municipal Administration of Hospitals

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes