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The efficacy and safety of acupuncture in cancer-related fatigue

Submission date	Recruitment status	[ ] Prospectively registered
09/04/2014	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
24/04/2014	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
24/07/2020	Cancer	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Fatigue is the most common symptom experienced by patients with cancer. Fatigue is under-reported and often not screened, partly because of a lack of availability of helpful treatments in the absence of reversible risk factors. The purpose of this study is to assess the therapeutic effects and safety of acupuncture for cancer-related fatigue in patients with breast cancer.

Who can participate?
Women with definite diagnosis of breast cancer who feel tired can participate in this study.

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 for 4 weeks. Participants in the control group will receive minimal acupuncture therapy for 4 weeks. They will complete some questionnaires at the start of the study and at fortnightly intervals to find out about any changes in fatigue level, sleep, appetite and emotion. They will be followed up for 1 month to assess long-term effectiveness.

What are the possible benefits and risks of participating?
All participants will receive free treatment for 1 month 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. The risks of taking part are minimal. Acupuncture is a very safe treatment when given by properly trained clinicians. Occasionally acupuncture can make people feel nauseous or faint or experience a temporary increase in pain 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 two locations:
1. Beijing Hospital of Traditional Chinese Medicine, China
2. Guang' anmen Hospital, China Academy of Chinese Medical Sciences, China

When is study starting and how long is it expected to run for?
The study will start in April 2014 and will end in April 2015.

Who is funding the study?
Beijing Administration of Traditional Chinese Medicine (China).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
JJ2011-04

Study information

Scientific Title
Efficacy and safety of acupuncture for cancer-related fatigue in patients with breast cancer: a randomized, single-blinded, controlled trial

Study objectives
To assess the therapeutic effects and safety on acupuncture for cancer-related fatigue in patients with breast cancer.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Beijing Hospital of Traditional Chinese Medicine Research Ethical Committee, 10/05/2012; ref: 201214

Study design
Randomised single-blind controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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

Interventions
The 40 eligible participants are randomly allocated to two different groups:
1. Participants in the intervention group will receive acupuncture therapy three times a week for 4 weeks
2. Participants in the control group will receive minimal acupuncture therapy three times a week for 4 weeks

All the patients will complete some questionnaires at the start of the study and at fortnightly intervals to find out about any changes in fatigue level, sleep, appetite and emotion. They will be followed up for 1 month to assess long-term effectiveness.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Revised Piper Fatigue Scale-Chinese Version (RPFS-CV), a multidimensional assessment tool for measuring the level of fatigue subjectively for patients with cancer. It will be assessed before the treatment, at 2 and 4 weeks during the treatment, and 4 weeks after the treatment.

Secondary outcome measures
1. Eastern Cooperative Oncology Group Performance Status (ECOG PS) .
2. Pittsburgh Sleep Quality Index (PSQI)
3. Simplified Nutritional Appetite Questionnaire (SNAQ)

4. The Hospital Anxiety and Depression Scale (HADS)
5. TCM symptoms scale
The outcome measures above will be assessed before the treatment, at 2 and 4 weeks during the treatment, and 4 weeks after the treatment.

Overall study start date
10/04/2014

Completion date
10/04/2015

Eligibility

Key inclusion criteria
1. Women patients with a definite pathologic diagnosis of breast cancer who had complete chemotherapy and/or radiotherapy at least 1 month before and mastectomy within 5 years
2. Stage I-III breast cancer with no evidence of recurrence and metastasis
3. Eastern Cooperative Oncology Group (ECOG) performance status 0-2
4. Anticipated survival time is more than 6 months
5. Aged 18-65
6. Patients who are suffering from at least moderate fatigue by Revised Piper Fatigue Scale-Chinese Version (RPFS-CV)
7. All patients provided written informed consent before enrollment

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Female

Target number of participants
40

Key exclusion criteria
1. Complicated with other primary tumors and serious heart, liver, kidney and hematopoietic system diseases
2. Pregnant women or women who are breastfeeding
3. Patients who had needle phobia
4. Patients who had low platelet count or suffered from a bleeding disorder (e.g., haemophilia)
5. Patients who had lymphoedema at the area of the acupuncture points
6. Patients who were on active treatment for anaemia (i.e., EPO or blood transfusions)

7. Patients who were receiving steroids to combat fatigue
8. Patients who had been diagnosed with depression, anxiety disorders, mental illness and cognitive disorders

Date of first enrolment
10/04/2014

Date of final enrolment
10/04/2015

Locations

Countries of recruitment
China

Study participating centre
No.23, Back Road of Gallery
Beijing
China
100010

Sponsor information

Organisation
Beijing Administration of Traditional Chinese Medicine (China)

Sponsor details
No.70, Front Road of Zaolin
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100053

Sponsor type
Other

ROR
https://ror.org/003regz62

Funder(s)

Funder type
Other

Funder Name
Beijing Administration of Traditional Chinese Medicine (China)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration