ISRCTN16408424 https://doi.org/10.1186/ISRCTN16408424

Acupressure of the ear for fatigue, sleep problems and anxiety in cancer patients treated with chemotherapy

Submission date
07/05/2018

Recruitment status
No longer recruiting

Registration date
10/05/2018

Overall study status
Completed

Last Edited
23/11/2020

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Cancer-related fatigue (CRF) is common in lung cancer patients treated with chemotherapy and this can affect the patient's quality of life. Auricular acupressure (stimulating acupuncture points on the ear without using needles or breaking the skin) has been increasingly used to manage symptoms in cancer patients.

Who can participate?
People aged 18-75 years who are receiving chemotherapy (drug treatment) for lung cancer

What does the study involve?
In the two intervention groups, patients will have a small ball-shaped seed or a magnetic ball taped to five acupressure points on their ear. They will press each seed or ball against the ear 4 to 6 times per session at 5 sessions per day. They will do this every day for 18 days to complete a cycle of therapy. They will have 3 days with no seed or balls taped to their ear before starting the next 18-day course. There are 3 18-days courses in the study. Patients in the control group will receive the usual care for lung cancer patients treated with chemotherapy.

What are the possible benefits and risks of participating?
There are no side effects linked with auricular acupressure reported previous studies. Participants will receive a certain amount of compensation for their time.

Where is the study run from?
First Affiliated Hospital of Soochow University

When is the study starting and how long is it expected to run for?
December 2016 to August 2018

Who is funding the study?
Suzhou Municipal Science and Technology Bureau

Who is the main contact?
Dr Tian Li, tianlisz@suda.edu.cn

Contact information

Type(s)
Scientific

Contact name
Dr Li Tian

Contact details
No. 188 Shizi street
suzhou
China
215006
+86 512 65221481
tianlisz@suda.edu.cn

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Auricular acupressure for cancer-related fatigue, sleep disturbance and anxiety in lung cancer patients undergoing chemotherapy

Study objectives
Auricular acupressure (AA) can alleviate cancer-related fatigue, sleep disturbance and anxiety in lung cancer patients

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the First Affiliated Hospital of Soochow University, 03/03/2017, 2017028

Study design
Randomised controlled trial

Primary study design

Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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
Fatigue, sleep disturbance and anxiety in lung cancer patients with no severe complications

Interventions
Those patients who met the study criteria were randomly assigned to one of three groups using computer-generated numbers.
Group A: auricular acupressure using Semen Vaccariae (SV, seed of cowherb [Vaccaria segetalis])
Disinfect the skin with 75% alcohol, dry the skin, and place a piece of tape with SV on the selected ear acupoint. Vertically press the SV until the patients report the feeling of swelling pain, continue to press each acupoint for 20 to 30 seconds, and press the five selected acupoints repeatedly and in turn 4 to 6 times for each session, with 5 sessions per day (i.e., in the morning, after each of 3 meals and before bedtime). Replace the SV tape every 3 days. One treatment course included six replacements, the interval between two consecutive treatment courses was three days, and the whole intervention length of the study was three treatment courses, i.e. three cycles of therapy.
Group B: auricular acupressure using magnetic beads
The intervention protocols for group B and group A were the same; the only difference was that magnetic beads were used in group B in place of SV.
Group C: routine care
Patients received routine care during hospitalization, and after discharge, regular telephone follow-up and home visits were performed.

Intervention Type
Other

Primary outcome measure
Cancer-related fatigue (CRF) was assessed by the Cancer Fatigue Scale - Chinese version (CFS-C) using a numerical rating scale ranging from 0 to 10, with 10 indicating severe CRF and ≥4 indicating clinically significant fatigue. CRF was measured at baseline and at the end of the whole intervention, i.e. after the patients received three cycles of therapy.

Secondary outcome measures
1. Sleep quality and quantity in the past month was assessed using the Pittsburgh Sleep Quality Index (PSQI)

2. Anxiety was assessed using the Self-rating Anxiety Scale (SAS)
Sleep disturbance and anxiety were measured at baseline and at the end of the whole intervention, i.e. after the patients received three cycles of therapy.

Overall study start date
01/12/2016

Completion date
31/08/2017

Eligibility

Key inclusion criteria
1. Aged 18-75 years
2. Receiving conventional chemotherapy for lung cancer
3. Diagnosed with CRF using the diagnostic standards of the International Statistical Classification of Diseases and Related Health Problems 10th Revision and showed CRF ≥4 on a 0-10 numerical rating scale
4. No infection, injury or ulcers around the acupoint
5. No previous participation in AA or any fatigue-related intervention
6. No cognitively impairment
7. Willing to participate

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
75 Years

Sex
Both

Target number of participants
75

Total final enrolment
100

Key exclusion criteria
Patients who had pleural effusion and other severe complications (such as severe anemia, severe organic diseases or dysfunction of heart, brain, or kidney) were excluded

Date of first enrolment
01/12/2016

Date of final enrolment
30/06/2017

Locations

Countries of recruitment
China

Study participating centre
First Affiliated hospital of Soochow University
No. 188 Shizi street
suzhou
China
215006

Sponsor information

Organisation
Suzhou Municipal Science and Technology Bureau

Sponsor details
No. 979 Renming Road
suzhou
China
215002
+ 86 512 65241084
szkjxm@szkj.gov.cn

Sponsor type
Government

ROR
https://ror.org/02vpk4745

Funder(s)

Funder type
Not defined

Funder Name
Suzhou Science and Technology Development Project (SYS 201526)

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal

Intention to publish date
31/08/2018

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2021	23/11/2020	Yes	No