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Traditional Chinese medicine (TCM) for cancer

Submission date 22/05/2008	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 29/05/2008	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 04/03/2009	**Condition category** Cancer	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
MCT-73503

Study information

Scientific Title
The effectiveness of traditional Chinese herbal medicine and Tai Chi on improving quality of life of cancer patients: a pilot randomised clinical trial

Study objectives
To examine the feasibility of conducting a large Canadian trial aimed at assessing the effectiveness of traditional Chinese herbal medicine (with specially tailored formulas) and Tai Chi on improving cancer patients' quality of life (QoL).

Hypothesis:
Patients receiving Chinese herbal medicine or Tai Chi will have more energy, more appetite and more overall quality of life than patients exposed to placebo or light physical exercise.

Please note that as of 04/03/2009 the anticipated start and end dates in this record were amended. The previous dates are as follows:
Initial anticipated start date: 30/06/2008
Initial anticipated end date: 30/12/2008

Please also note that at this time, the disease was amended from non-small cell lung cancer to colorectal cancer.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of British Columbia (UBC) BC Cancer Agency (BCCA) Research Ethics Board approved on the 5th April 2007 (ref: H06-03861); most recent BC Cancer REB and NHPD approval (change of the study population) received in January 2009.

Study design
Single-centre, factorial 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
Colorectal cancer/fatigue, nausea, vomiting, anorexia/Chinese medicine for improving cancer patients' quality of life

Interventions
Factorial randomised controlled trial with two factors being herbal treatment (double-blinded, placebo-controlled) and Tai Chi exercise (group mild exercise-controlled).

The experimental interventions are:
1. Tailored TCM herbal decoction (twice daily for three months), based on 58 TCM herbs /products (added 04/03/2009)
2. Tai Chi exercise

The control interventions are:
1. Placebo decoction (twice daily for three months)
2. Control for Tai Chi group intervention is group mild exercise

Contact for public queries:
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Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Tailored TCM herbal decoction

Primary outcome measure
Primary outcome:
The feasibility as assessed through several factors, such as co-interventions, percentage of participation and withdrawal/non-compliance, preparing decoction/placebo and keeping blinding, the possibility to stratify, reasons for not participating, male/female difference regarding compliance and participation.

Primary clinical outcome: Quality of life
Primary outcome measuring time point: baseline, monthly, three months post-intervention

Secondary outcome measures
1. Fatigue
2. Nausea and vomiting
3. Anorexia
4. Insomnia
5. Anxiety and depression

Secondary outcome measuring time point: except for anxiety and depression which will be measured at baseline and the end of third month, the rest will be measured at baseline and monthly.

Overall study start date
01/01/2009

Completion date
30/01/2010

Eligibility

Key inclusion criteria
Amended 04/03/2009:
Point two of the inclusion criteria has been amended as follows:
2. Participant has been diagnosed with colorectal cancer

Initial information at time of registration:
1. Male or female participants greater than or equal to 18 years
2. Participant has been diagnosed with non-small cell lung cancer
3. Participant has completed chemotherapy treatments
4. Participant is experiencing fatigue, anorexia, or uncontrolled nausea or vomiting
5. Participant has enough strength to perform Tai Chi and mild exercises (Eastern Cooperative Oncology Group [ECOG] Performance Status 0,1,or 2)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
80

Key exclusion criteria
Amended 04/03/2009:
1. Severe allergy to herbs, plants or plant products
2. Severe diabetes, severe heart failure, liver failure, kidney failure or any severe concomitant conditions that could affect the follow-up or quality of life
3. Taking any drug that potentially increases the risk of bleeding
4. Pregnant or planning to get pregnant in the following three months
5. Breastfeeding or planning to breast feed in the following three months
6. Severe anaemia (haemoglobin less than 9 g/dL)
7. Cancer has spread to the long bones or spine

8. Exposure to TCM treatment within the last 2 weeks
9. Practicing Tai Chi exercises within the last months
10. Difficulty understanding the consent form

Initial information at time of registration:
1. Allergy to herbs, plants or plant products
2. Severe diabetes, severe heart failure, liver failure, kidney failure or any severe concomitant conditions that could affect the follow-up or quality of life
3. Pregnant or planning to get pregnant in the following three months
4. Breastfeeding or planning to breast feed in the following three months
5. Severe anaemia (haemoglobin less than 9 g/dL)
6. Cancer has spread to the bones
7. Already on TCM treatment
8. Difficulty understanding the consent form

Date of first enrolment
01/01/2009

Date of final enrolment
30/01/2010

Locations

Countries of recruitment
Canada

Study participating centre
Child and Family Research Institute
Vancouver, British Columbia
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V6H 3V4

Sponsor information

Organisation
University of British Columbia (Canada)

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2075 Wesbrook Mall
Vancouver, British Columbia
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V6T 1Z1

Sponsor type
University/education

Website
http://www.ubc.ca/

ROR
https://ror.org/03rmrcq20

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: MCT-73503)

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