

# Traditional Chinese medicine (TCM) for cancer

<b>Submission date</b> 22/05/2008	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 29/05/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 04/03/2009	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

**Protocol serial number**  
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

**Study type(s)**

Treatment

**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(s)**

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

### **Key secondary outcome(s)**

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.

### **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

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

### **Sex**

All

### **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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## Sponsor information

**Organisation**

University of British Columbia (Canada)

**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

Individual participant data (IPD) sharing plan

## **IPD sharing plan summary**

Not provided at time of registration