Protocol title:	A feasibility study of Chinese herbs to manage cancer-related symptoms in patients with advanced non-small-cell- lung cancer
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Title: A feasibility study of Chinese herbs to manage cancer-related symptoms in patients with advanced non-small-cell- lung cancer

The Principal Investigator of this study is Dr. Thomas Jagoe

INFORMED CONSENT FORM

Introduction:

You are invited to participate in a research study because you have Non Small Cell Lung Cancer (NSCLC). You have the right to know about the purpose and procedures that are to be used in this research study, and to be informed about the potential benefits, risks, compensation, and discomfort of this research.

Before you give your consent to be a participant, it is important that you read the following information and ask as many questions as is necessary in order to understand what you will be asked to do, should you decide to participate. It is also important that you understand that you do not have to take part in this study. Whether or not you decide to take part, you will receive the best possible care to which you are entitled. If you decide that you want to take part, you will be asked to sign this consent form and you will be given a copy to keep.

Purpose of study:

This is a clinical research study designed to evaluate if it is feasible to take a Chinese herbal formula for 6-weeks to manage symptoms commonly experienced by patients with advanced stage lung cancer.

The study will be carried out at the Peter Brojde Lung Cancer Centre of the Jewish General Hospital in Montreal. Should you agree and are eligible to participate; you will be given a supply of Chinese herbal capsules or sachets during the study.

Lung cancer patients often experience a variety of different symptoms at different times. These can include weight loss, pain, fatigue, coughing, and anxiety. Conventional treatments like pain-killers and other medication as well as psychological support and even palliative chemotherapy and radiation are used with some effect. However even these treatments may sometimes be accompanied by other unpleasant effects. The medical literature suggests that selected Chinese herbs may help manage these symptoms and we want to test whether this is true for the patients here at the Peter Brojde Lung Cancer Centre.

The Chinese herbal formula we will use consists of a recipe of 23 carefully selected and blended herbs. The herbs will be given in capsule or sachet form that needs to be taken regularly. There are minimal known adverse effects and no documented evidence of actual drug-herbal interactions. However certain western medications should either be avoided or monitored closely during the study. Your study doctor will discuss this with you.

What is Expected of you as a Research Participant

You will:

- Allow us to collect medical information about you and your condition before you start Chinese herbs
- Take the capsules or sachets (your choice) as instructed by the study coordinator (3 times a day, after the meal). The sachets can be mixed with up to 200ml of water (about one glass of water) or with yogurt.
- Attend your study appointments. If you cannot keep an appointment, contact the study coordinator to reschedule as soon as you know that you will miss the appointment.
- Tell the study coordinator about any side effects, doctor visits, or hospitalizations that you may have.

- Keep the Chinese herb capsules/satchets in a safe place, for your use only, and away from children.
- Keep a diary to record when you took your study medication
- While participating in this research study, you should not take part in any other research project without approval from your study doctor. This is to protect you from possible injury arising from such things as extra blood drawing, the possible incompatibility between research drugs, or other similar hazards.
- Ask questions as you think of them.
- Tell your doctor if you change your mind about staying in the study.
- If you decide to participate in this research study you will have to sign this consent and form.
- Complete questionnaires at intervals during the study
- You will be allowed to maintain your concomitant medications during the trial with exception of over-the-counter herbal supplements.

Procedures:

After you sign this form, you will be asked to complete some questionnaires about any current symptoms before, during and at the end of the 6-week study. This might take 20-30 minutes of your time. A list of all your current medications, supplements, vitamins, naturopathic medications needs to be shared with the research assistant (RA) before the Chinese herbs can be given. Any anticipated changes to these supplements need to be discussed with the study doctor; any changes in your medications need to be communicated immediately to the RA. You must stop any other herbal treatments during the course of this study because we want to minimize the risk of any potential drug-herbal interactions.

The research assistant will provide you with 2-weeks supply of capsules or sachets, and this will be repeated twice more until the study is completed after 6 weeks' treatment. You will also receive a diary to record when you took the study treatments or any missed doses. The diary must be given back to the RA every two weeks when you get your next supply of study treatment and at the end of the study.

Treatment visits

The duration of the study is 6 weeks. During that time you will have to come for screening visit and another 4 visits 2-weeks' apart. At each visit you will have:

- Regular physical exam

- Review of your symptoms and current medications
- Return your diary and get a new one
- Asked to complete the questionnaires
- Dispensed 2 weeks supply of capsules/sachets

Risks, Discomforts and Side-Effects:
You do need to come to clinic to be monitored every two weeks.

So far, the side effects of Chinese herbs range are generally minimal or unknown. A number of recent clinical studies have suggested that Chinese herb treatments such as the one that will be used in this study can help patients with cancer feel better even during their cancer treatment. However, there are also reports suggesting that patients taking Chinese herbs on their own (without medical supervision) can sometimes experience side-effects especially if they take large doses for long periods of time. In these reports less than 1 in 10 patients have reported side-effects such as redness of the skin, itching, dizziness or gastro-intestinal symptoms (e.g. diarrhea, stomach ache and cramping). There may be unknown risks in taking these Chinese herbs that have never been documented. Although, there is no documented evidence of actual drug-herbal interactions, be aware that the potential for drug-herbal interactions is possible.

Reproductive risks

Women only:

You may not participate in this study if you are pregnant or become pregnant, or if you are currently breast-feeding. You or your child may be exposed to an unknown risk.

If you are a woman who is able to become pregnant, it is expected that you will use an effective method of birth control during study drug treatment and for 90 days after the last dose to prevent exposing your baby to a potentially dangerous unknown risk.

You must agree to use birth control method(s) judged to be effective by your doctor and which will not interfere with the proposed study. You must accept the risk that pregnancy might still result despite the responsible use of a reliable method of birth control. You agree to notify the investigator as soon as possible of any failure of proper use of your birth control method, or if you become pregnant (during the study, or within 90 days of stopping treatment), either of which may result in your being withdrawn from the study. Your doctor will advise you of the possible risks to your unborn child and options available to you.

Men only:

It is expected that you will use an effective method of birth control during study drug treatment and for 90 days after the last dose. If your partner becomes pregnant while you are taking part in this study, or within 90 days after stopping treatment, you should inform your doctor as soon as possible.

Benefits:

The main benefits associated with participating in this study is in helping us to evaluate the feasibility and safety of the Chinese herbs so that we may initiate a larger study that can evaluate the effectiveness of the herbs in treating symptoms. While we can not guarantee that you will benefit from your participation in this study, there is the possibility that these herbs may in fact help to improve some of your symptoms thereby enhancing your overall sense of well being.

Alternative to Study Participation:

If you choose not to participate in this study you will continue to be assessed and followed by your usual oncology team who will discuss alternative ways to help you with any symptoms. Your doctor will be able to discuss with you all alternative treatments available to you.

Voluntary participation/withdrawal:

Your participation in this clinical research is voluntary. You may refuse to participate or may discontinue your participation at any time without explanation and without penalty or loss of benefits to which you are otherwise entitled. If you decide not to participate or if you discontinue your participation, it will not affect the care you receive for your cancer in any way. In the case of withdrawal, information collected to that point will be used to preserve the quality and integrity of the study.

If you want to stop taking part in the study, you must tell your study doctor. He/she will explain the best way for you to safely end your participation in the study. If you decide to withdraw from the study, you will be asked to undergo a final study visit. It is important to tell the doctor if you are thinking about stopping, so any risks from the study drugs can be evaluated by your doctor. Another reason to tell your doctor that you are thinking about stopping is to discuss what follow up care and testing could be most helpful for you.

In addition, your participation in this study may be stopped with or without your consent at any time for any of the following reasons:

- Failure to follow the instructions of your doctor and/or study staff.
- Your doctor decides that continuing your participation could be harmful to you.
- Pregnancy
- Your physician prescribes you a treatment not permitted within this study
- The study is cancelled (or for other administrative reasons).

If your participation in this study is stopped, the reasons will be discussed with you. Likewise, you may stop being the study at any time, even if you have already started taking your capsule or sachets.

New Information Learned:
Any new findings that become available during the course of this study that could affect your willingness to participate will be told to you in a timely manner so that you may decide if you want to stay in this study. In the event that you withdraw or your participation in this study is ended, all information collected for the purpose of this study may be used, up to the point of your withdrawal as described in this consent form, in order to guarantee the scientific integrity of the study. If you withdraw your consent for participating in this study, further study procedures will end.

Confidentiality:
For this study, the study doctor will need to access your personal health records for health information such as past medical history and test results.

The health information collected as part of this study will be kept confidential unless release is required by law and only used for the purpose of the research study as stated in the study objectives above. All identifying information will be coded and kept behind locked doors, under the supervision of Dr. Thomas Jagoe, and not transferred outside of the hospital unless release is required by law. Your information will be collected until the end of the study and stored for a period of 25 years. This consent form will be placed in your medical record.

To make sure that the health information collected in this study is accurate, it will need to be checked from time to time against your medical records. A limited number of representatives from the Research

Ethics Committee, government regulatory authorities including Health Canada, may need to see these records in order to monitor the research and verify the accuracy of the study data.

By signing this consent form, you are allowing the collection, use and disclosure of the information contained in your medical records for the purposes of this study and as explained in this consent form. Any research data collected about you during this study will not identify you by name, only by your initials and a coded number. Your name will not be disclosed outside the research clinic. The results of the study may be used in presentations or published in scientific reports but your name or identity will never appear.

If you withdraw from the study, the medical information which is obtained from you for study purposes will not be destroyed for as long as it is necessary to maintain patient safety and meet regulatory requirements. You have a right to check your health records and request changes if the information is not correct.

For safety purposes, and in order to communicate information that is required in order to protect your well-being, the principal researcher of this study will keep separate from the research documents your personal information including your name, contact information, the date your participation in the study began and when it ended for the period of one year after the end of the study. None of the information collected from this register will be for research purposes and all information will be destroyed after 12 months following the end of your participation in this study.

You have the right to look at your study file in order to check the information gathered about you and to correct it, if necessary, as long as the study researcher or the institution keeps this information. However, you may only have access to certain information once the study has ended so that the quality of the research study is protected.

Costs/Compensations

You will not be paid for your participation in this study. There will be no costs to you for participating in this study. The Chinese herbs formula and research procedures will be provided to you free of charge. Taxi vouchers will be provided to you to cover the cost of getting to and from the hospital for 3 out of 5 visits, the remaining two visits are considered a standard care visits.

If you suffer an injury as a result of participating in the study, necessary medical treatment will be available at no additional cost to you. Unless required by law, compensation for such things as lost wages, disability or discomfort due to such an injury will not be offered. However, by signing this consent form you do not give up any of your legal rights (including the right to seek compensation for an injury resulting from your participation in the study) nor relieve the sponsor, institution and investigator from their professional and legal responsibilities.

Information source

If you have questions about taking part in this study, or suffer a research-related injury, you can speak to:

- Thi Tran (TCM practitioner) at (514) 340-8222 ext 8590
- Dr. Thomas Jagoe (principal investigator at (514) 340-8203
- The pulmonologist on call 24h/24 at 514-340-8232.

You can speak to someone who is not involved with the study at all, but who can advise you on your rights as a research participant. That person is the Local Commissioner of Complaints & Quality of Services, Rosemary Steinberg (514) 340-8222, extension 5833.

Declaration of consent

TITLE: A feasibility study of Chinese herbs to manage cancer-related symptoms in patients with advanced non-small-cell- lung cancer

I have read this consent form and I voluntarily agree to participate in this study. I have had the opportunity to ask questions and all my questions have been answered to my satisfaction. I have been given sufficient time to consider the information and seek advice should I choose to do so.

I agree that my family doctor will be told about my participation in this research (please circle one and initial):

YES NO INITIALS ☐

Name of Family Doctor:_____

I authorize the principal investigator and the research assistant to collect and use my personal information for the purpose and in the manner mentioned above. I understand I have the right to access my personal information and make corrections subject to the applicable laws and regulations. This consent is valid until the study is completed. However I may discontinue my participation in the study at any time without loss of benefits or treatments to which I am otherwise entitled. I will be given a signed copy of this consent form. By signing this consent form I do not give up any of my legal rights.

_____	_____	_____
Participant	Signature	Date
_____	_____	_____
PI/Research Assistant	Signature	Date