



**Northern Sydney & Central  
Coast  
Area Health  
Royal North Shore Hospital**



## Participant Information Sheet – Clinical Trial

Dear Participant,

You are being asked to consider taking part in a research project at the Centre for Complementary Medicine Research (CompleMED) at the University of Western Sydney and the Gastrointestinal Investigation Unit at the Royal North Shore Hospital, titled

**“Clinical evaluation of Chinese herbal medicine for Constipation-predominant Irritable Bowel Syndrome” (C-IBS Trial)**

### What is this research project about?

This research project has been funded by the Australian National Health and Medical Research Council and will test whether Chinese herbal medicine is useful for treating constipation predominant Irritable Bowel Syndrome (C-IBS). About 160 people will take part in the trial, and they will be randomly divided into 2 groups. Group 1 will receive plant based capsules with the active Chinese herbal medicine, and Group 2 will receive placebo (also called dummy) capsules. This will allow us to compare if the active herbal medicine has any positive effects in relieving the symptoms of C-IBS.

### Why is this project needed?

Over 10% of Australians have IBS. It is the most common chronic medical disorder of the digestive tract, and around 40% of all IBS patients have C-IBS. C-IBS has multiple symptoms, including abdominal pain, bloating, constipation and changed bowel habits. IBS significantly impacts the quality of life of sufferers, placing restrictions on work and social activities. There is currently no ideal treatment for IBS and its symptoms. The Chinese herbal formulation being tested has been designed to address the multiple symptoms of C-IBS. You are being asked to consider this trial because you have C-IBS.

### What will my participation involve?

Your GP or gastroenterologist will complete a checklist to confirm your diagnosis of C-IBS and make sure you meet all the criteria to be able to take part in the trial. If you are suitable, your doctor will refer you into the trial and the research staff will then contact you to arrange your first appointment.

At your first visit, the research team will talk to you in more detail about the trial and your suitability. If enrolled in the trial, all other trial visits will be done with trial researchers at a Sydney trial site of your choice.

You will be required to make 4 brief visits to your chosen clinical trial site over 16 weeks, where you will be asked to complete some questionnaires and will be given the trial medication. The first appointment will take up to an hour, and following appointments around 30 minutes. There is one 5 minute phone questionnaire. You will visit the clinic every 4 weeks while you are taking the trial medication, then 8 weeks after finishing the trial medication. An appointment schedule is listed below:

<b>Appointment 1</b> <i>(Commence Treatment)</i> Week 0	<b>Phone Questionnaire</b> Week 2	<b>Appointment 2</b> Week 4	<b>Appointment 3</b> <i>(End of Treatment)</i> Week 8	<b>Appointment 4</b> <i>(Follow Up)</i> Week 16
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If you agree to take part in the trial, you must attend all appointments and you will be required to take all study medications which includes 5 capsules, twice per day for 8 weeks. We will call you one week after starting the trial medication to check if you have any new questions about the study, but you can contact research staff at any time throughout the trial if you have any further questions.

During the study, you must not take any of the following medications: any narcotic analgesic such as codeine, morphine or tramadol, any antispasmodic bowel medication such as Buscopan, Colofac or peppermint oil, or any regular laxative. If you regularly use a fibre based laxative such as bran or Metamucil, you may continue to take this throughout the study.

There are no expected costs for enrolling in the trial and at the end of the trial you are entitled to be reimbursed \$20.00 per visit for travel related expenses in attending each of the four face-to-face appointments.

A blood test may be required before starting the trial (if you do not have the results of one recently) to check full blood count, liver and kidney function to make sure it is safe for you to go into the study. You will have a blood test when you finish taking the tablets at any Douglas Hanly Moir pathology collection centre near you, free of charge. After recording your results, the blood sample will be destroyed.

### **What are the potential benefits?**

The trial medication is made up of Chinese herbal ingredients which have been used in Chinese and Asian culture as medicines for the relief of common symptoms associated with IBS for centuries. By combining the uses of different herbs into one formula, we have tried to create a single herbal medicine that relieves the variety of common symptoms associated with C-IBS. Although there is no guarantee of any benefit, some volunteers may experience a reduction in abdominal pain, bloating, flatulence and have improved bowel function. By taking part in this trial you will be assisting to improve knowledge about the best treatments for C-IBS.

### **What are the potential risks and alternatives?**

Sometimes, mild side effects may occur such as increased bowel activity, mild gastrointestinal effects, dizziness or headaches. Other potential risks could include minor discomfort and bruising associated with blood tests. If an adverse event occurs, it may be necessary to change the dose or stop the trial medicine and you may be withdrawn from the trial. You can call the Trial Coordinator at any time, if you have any concerns.

All the herbal ingredients and dosages used in this trial are approved as suitable for human consumption by the Australian Therapeutic Goods Administration (TGA) and these herbs are available over the counter, so the risk of these effects is minimal. However as an added precaution it is important that women participating in this study are not pregnant and do not become pregnant during this study, please advise the research team immediately if you think you might be pregnant. If necessary, reliable contraception should be used during the course of this study (such as oral or implanted contraception, an IUD or have had a tubal ligation if you are female, or condoms if you are male). If you are a woman of childbearing age and there is any possibility that you are pregnant, the researchers will need to perform a urine pregnancy test before you start in the study.

Alternate treatment options for C-IBS may be available and you are able to discuss these with your doctor. If you are suffering from persistent constipation for at least four consecutive days despite the trial medication, please contact your study doctor who will advise on an appropriate laxative.

### **What are my rights if I participate?**

You should make sure that you completely understand all the implications, risks and benefits of taking part in the trial, and that all your questions are answered. You will receive a copy of this Participant Information Sheet and a signed Consent Form to keep. If at any time information becomes available that might influence your decision to stay in the trial, you will be informed immediately.

Your confidentiality and privacy is important to CompleMED. The research team will collect personal and health information (eg, your gender, age and medical conditions), as well as other information as part of the trial. Research staff and others who work with the trial such as external monitors or the Human Research Ethics Committee (HREC) will have access to this information to check the study is conducted properly. All staff who see this information will keep it strictly confidential. Your data will be securely stored and identified by a code number along with your initials. The results obtained in this study will be published in medical journals and conferences however the details will not identify individual participants. The results of the trial and which group you were assigned to (active or placebo) will be sent to you when the study finishes.

Please understand that while your participation would be sincerely appreciated, **you are under no obligation to take part in the study**. If you don't agree to take part, or you do agree but later change your mind or leave the study for any reason, there will be no prejudice to your ongoing treatment or your relationship with the researcher or referring doctor. If information becomes available which might influence your continued participation in the trial, or the study needs to be stopped, you will be informed immediately. This study is covered by clinical trial protection insurance, please contact the research team if you require more information on the insurance provisions for the trial.

This study has been approved by the University of Western Sydney Human Research Ethic Committee or the University of Western Sydney Human Research Ethics Panel. If you have any complaints or reservations about the ethical conduct of this research, you may contact the Ethics Committee through the Research Ethics Officer, nominated as Complaint Officer [k.buckley@uws.edu.au](mailto:k.buckley@uws.edu.au) (Tel (02) 4736 0883). Any issues you raise will be treated in confidence and investigated fully, and you will be informed of the outcome.

This study has also been approved by the Hawkesbury Human Research Ethic Committee of Northern Sydney Central Coast Health (NSCCH). Any person with concerns or complaints about the conduct of this study should contact the Research Office who is nominated to receive complaints from research participants. You should contact them on 02 9926 8106 and quote [Protocol 0810-214M].

For any questions or concerns please contact the Trial Coordinator in the first instance:

	<b>Trial Coordinator</b> Ms Suzannah Bouchier	<b>Chief Investigator</b> Professor Alan Bensoussan	<b>Royal North Shore Hospital</b> <b>Chief Investigator</b> Associate Professor John Kellow
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**Thank you for your interest in this study!**