Participant Information Sheet/Consent Form

Title	A pilot pragmatic randomised controlled trial on acupuncture for cancer pain
Chief Investigator/Senior Supervisor	Charlie Changli Xue
Associate Investigator(s)/Associate Supervisor(s)	Anthony Lin Zhang, Haibo Zhang, Brian H May
Principal Research Student(s)	Yihan He

What does my participation involve?

1 Introduction

You are invited to take part in this research project, which is called *a pilot pragmatic randomised controlled trial on acupuncture for cancer pain*. You have been invited because you have been admitted to the oncology department. Your contact details were obtained by the admission card you completed when you were enrolled.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the processes involved with taking part. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative or friend.

Participation in this research is voluntary. If you don't wish to take part, you don't have to.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

- Understand what you have read
- Consent to take part in the research project

You will be given a copy of this Participant Information and Consent Form to keep.

2 What is the purpose of this research?

For cancer patients, pain is a distressing clinical symptom with an overall prevalence rate more than 70%. The National Comprehensive Cancer Network (NCCN®) Guidelines for adult cancer pain indicate that acupuncture and related therapies may be valuable additions to pharmacologic interventions for pain management.

A pragmatic randomised controlled trial will be conducted to evaluate the effectiveness of acupuncture as an adjunctive therapy to routine medicine and usual

care for cancer pain. The study design will incorporate individualised treatment flexibility in a real-world setting, which will be more appropriate to acupuncture research and provide realistic estimates of acupuncture effects. The principal objectives of this pilot trial are to provide data for sample size calculations, explore the feasibility of conducting a larger study in the hospital setting, identify challenges, and refine the protocol for the full-scale pragmatic randomised controlled trial.

Unlike most traditional randomised controlled trials which test a hypothesis under ideal conditions or determine causes and effects of treatment, pragmatic randomised controlled trials compare treatments under everyday clinical conditions, with the aim of improving practice by informing clinical and policy decisions directly. They are characterised by more representative samples because there is less restriction on eligibility criteria, real-world treatments using flexible protocols and local customization, and brief outcome assessments so data can be easily collected in clinical settings.

The results of this research will be used by the researcher Yihan He to obtain a PhD (Complementary Medicine) degree.

This research has been initiated by the researcher Professor Charlie Changli Xue

This research has been funded by Guangdong Provincial Academy of Chinese Medical Sciences, China, and RMIT University through the China-Australia International Research Centre for Chinese Medicine as well as PhD scholarship support to the principal research student provided by the School of Health and Biomedical Sciences, RMIT University.

This research is being conducted in the oncology department of Guangdong Provincial Hospital of Chinese Medicine.

3 What does participation in this research involve?

If you decide to take part in the research project, you will first be given a questionnaire asking about your pain degree; this will determine if you are eligible to take part. Completing the questionnaire will take approximately 10 minutes.
If the screening questionnaire shows that you meet the requirements, then you will be able to participate in the research project. The screening questionnaire may show that you cannot participate in the research project.

If you are involved in the study, you will be required to do the following:

- To sign this informed consent form
- To complete the numerical rating scale (NRS) for assessment of pain degree and the Chinese version of the Edmonton Symptom Assessment System (ESAS) for assessment of general symptoms. You will be asked to respond to questions regarding your pain and general symptoms at the time of

hospitalization. It should not take more than 30 minutes to complete the questionnaire.

- To report current regular pain medication dosage, rescue medication dosage in one week previous being enrolled in the study; and any breakthrough pain and rescue medication used or adverse events whenever they happen.
- To receive acupuncture treatments by professional acupuncturist during your hospitalization period: about 30 minutes each session, every day during the opioid titration period and once every two days after the goals of analgesia are achieved.
- To complete a short questionnaire regarding your experiences during the trial including their satisfaction with all the treatments you received, the effectiveness the pain relief you achieved, and your experiences and opinions on the acupuncture treatment (if received) before you discharge.

There are no costs associated with participating in this research project, nor will you be paid.
However, you may be reimbursed for any reasonable travel, parking, meals and other expenses associated with the research project visit.

4 Other relevant information about the research project

- 40 participants will be taking part in the project overall.
- The acupuncture group will receive usual inpatient care and acupuncture therapy while the control group will receive usual inpatient care only.
- The project will involve Guangdong Provincial Academy of Chinese Medical Sciences, China, and RMIT University through the China-Australia International Research Centre, in which the researchers are engaged.

5 Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your relationship with the researchers or with RMIT University.

Submitting your completed questionnaire is an indication of your consent to participate in the study. You can withdraw your responses any time if you change your mind about having them included in the study, before we have analysed and published the results.

6 What are the possible benefits of taking part?

We cannot guarantee or promise that you will receive any benefits from this research; however, you may appreciate contributing to knowledge. Possible benefits may include:

- You will receive free acupuncture treatments by the professional acupuncturist with the potential benefits of alleviation of pain symptom and improvement of quality of life.
- You will make a contribution towards developing a promising and effective therapy for cancer pain that may benefit scientific community and the society in the future.

7 What are the risks and disadvantages of taking part?

Although acupuncture is a relatively safe treatment with a low risk of side effects, you may suffer from:

- Mild and temporary adverse effects, such as bleeding, haematoma;
- Or serious adverse events, such as vertigo, palpitations, local infection, which are rare occurrences.

You may feel that some of the questions we ask are stressful or upsetting. If you do not wish to answer a question, you may skip it and go to the next question, or you may stop immediately. If you become upset or distressed as a result of your participation in the research project, members of the research team will be able to discuss appropriate support for you.

8 What if I withdraw from this research project?

If you do consent to participate, you may withdraw at any time. If you decide to withdraw from the project, please notify a member of the research team.

You have the right to have any unprocessed data withdrawn and destroyed, providing it can be reliably identified.

9 What happens when the research project ends?

You can contact the researcher for the results of the research by email (s3585975@student. rmit.edu.au). You will be provided with a summary of the results approximately three months after the research project is completed.

How is the research project being conducted?

By signing the consent form you consent to the research team collecting and using information from you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. The study data will be coded so that it will not be linked to your name. Your identity will not be revealed while the study is being conducted or when the study is reported in scientific

journals. All the data sheets that have been collected will be stored in a secure place. Any information that is obtained in connection with this study and that can be identified with you will remain confidential and will be disclosed only with your permission or as required by law. The information received during the project will only be used for evaluation, promotion and/or disciplinary purposes.

It is anticipated that the results of this research project will be published on scientific journals and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in the way of data that you cannot be identified, except with your express permission.

11 Who is organising and funding the research?

This research project is being conducted by Charlie Changli Xue, Anthony Lin Zhang, Haibo Zhang, Brian H May and Yihan He.

Competing interests: None declared.

12 Who has reviewed the research project?

This research project has been approved by the Institutional Ethics Committee of Guangdong Provincial Hospital of Traditional Chinese Medicine. Also, the management and the Scientific Committee of Guangdong Provincial Hospital of Traditional Chinese Medicine have granted written approval for the study. All parts of the study will be conducted according to internationally accepted ethical principles.

13 Further information and who to contact

If you want any further information concerning this project, you can contact the researcher on (020) 81887233-34829 or any of the following people:

Research contact person

Name	Yihan He
Position	Principal Research Student
Telephone	+86 1501 310 5897; +61 0478 862 438
Email	s3585975@student.rmit.edu.au

14 Complaints

Should you have any concerns or questions about this research project, which you do not wish to discuss with the researchers listed in this document, then you may contact:

Reviewing HREC name	the Institutional Ethics Committee of Guangdong Provincial Hospital of Traditional Chinese Medicine
HREC Secretary	Xiaoyan Li
Telephone	020-81887233-35943
Email	szyllwyh@163.com
Mailing address	Research Ethics Co-ordinator the Office of the Institutional Ethics Committee Guangdong Provincial Hospital of Chinese Medicine No.111 Dade Road Guangzhou, Guangdong Province, China (510120)

Consent Form

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Research Student(s)	Yihan He

Acknowledgement by Participant

I have read and understood the Participant Information Sheet.

I understand the purposes, procedures and risks of the research described in the project.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the project without affecting my relationship with RMIT.

I understand that I will be given a signed copy of this document to keep.

Name of Participant (please print) _____

Signature _____ Date _____

Declaration by Researcher†

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Researcher† (please print) _____

Signature _____ Date _____

† An appropriately qualified member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.