

# **Informed Consent form**

**IRB reference number: UW 20-480**

**Clinical study of School of Chinese Medicine, the University of Hong Kong**

*(Information Sheet and consent forms (English version). Version no.07 dated 2020.10.29)*

**This Informed Consent Form has two parts:**

- **Information Sheet (to share information about the research with you)**
- **Certificate of Consent (for signatures if you agree to take part)**

**You will be given a copy of the full Informed Consent Form**

## ● **General information**

This Informed Consent Form is for participants who are willing to participate in our clinical research. The title of our research project is

**Based on the theory of “body constitution of Chinese Medicine” and “combination of prescription and syndrome” to improve COVID-19 susceptible body constitution of residents in Hong Kong.**

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Funding Support: Chinese Medicine Development Fund, Hong Kong

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Relevant medical treatment at the clinical trial site:  
Researcher: Lai Yuen Kwan Agnes, Zhang Cheng, Cheng Chien-shan. Li Sha

Names and addresses of clinical laboratories:

- 1) HKU Central Clinic address: Room 703, 9 Queen's Road Central, Hong Kong
- 2) HKU Sassoon Clinic address: G/F, School of Chinese Medicine, 10 Sassoon Road, Pokfulam, Hong Kong

## **PART I: Information Sheet**

### **Introduction**

I am an examiner of this project from School of Chinese Medicine, HKU. We are doing research on the potential prevention of COVID-19 by Chinese medicine. I am pleased to show you the information and invite you to be part of this research. You do not have to decide today whether or not you will participate in the research. Before you decide, you can talk to anyone you feel comfortable with about the research. There may be some words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain. If you have questions later, you can ask us later.

In brief, Chinese medicine has been used for thousands of years in the treatment of epidemic diseases. Through the long-term struggle with the epidemic, Chinese Medicine have accumulated and explored a lot of prevention and control experience, including a profound understanding and a unique theoretical system of the cause, pathogenesis, transmission, prevention and control of the epidemic. The National Health Commission and Chinese Medicine development Fund in Hong Kong are also advocating the research on the prevention and treatment of COVID-19. For the modern measures of epidemic prevention, it includes three approaches: cutting off pathogens, controlling transmission routes, and reducing susceptible populations. However, although it is widely authorized and promoted in mainland China. So far, the preventive measures of Chinese medicine for COVID-19 has not been included in the medical system of Hong Kong, Therefore, it is of great clinical significance to further develop a preventive measure for COVID-19 by Chinese medicine for reducing susceptible populations. According to “Diagnosis and treatment of COVID-19 (新型冠狀病毒肺炎診療方案)”, Lancet report, and the experience of professional Chinese medicine physician, the median susceptible population of COVID-19 is 49 years old (interquartile range is 41-58 years old). The body constitution of this kind of patients is mainly divided into " Deficiency of Qi and Yang " or "Deficiency of Qi and Yin". Therefore, "Invigorating Qi and Yang, invigorating Qi and Yin" can be regarded as the primary strategy of preventing COVID-19 by Chinese medicine. Considering that the risk of COVID19 infection is distributed in different age groups, the inclusion age of this subject is adults aged 18 and above, and has the physical characteristics of "deficiency of both qi and Yang" or

"deficiency of both qi and Yin". After a series of questionnaire surveys and blood sample collection, we can estimate subjects with body constitution is more likely to infect COVID-19. If your body constitution is Qi deficiency accompanied by Yin deficiency or yang deficiency, you will undergo Chinese medicine in various groups.

### **Purpose of the research**

#### ● **Primary outcomes:**

Evaluation of the improvement of COVID19-related susceptible body constitution by Chinese Medicine treatment

#### ● **Secondary outcomes:**

1. Clarify the distribution of COVID-19 susceptible residents in Hong Kong by questionnaires
2. Identify the changes of biomarker which may be potentially fluctuated by COVID19 infection

### **Type of Research Intervention**

This research will involve an oral administration of the Chinese medicine.

### **Participant selection**

#### **Inclusion criteria**

- (1) Age 18 or above, regardless of gender;
- (2) For COVID-19 susceptible individuals, according to the criteria of "Self-test for classification and judgment of body constitution by TCM theory (中醫體質分類判定自測表)", subjects with deficiency of Qi with either Yin or Yang will meet the inclusion criteria;
- (3) No previous allergy to traditional Chinese medicine;
- (4) Be able to understand Chinese questionnaire;
- (5) Willing to participate in the study.

#### **Exclusion criteria**

- (1) Not meet the terms in the inclusion criteria;
- (2) Syndrome types are not related to "deficiency of Qi and Yang" or "deficiency of Qi and Yin";
- (3) Suspected or confirmed COVID-19 patients;
- (4) Fever, body temperature > 37°C with cough and other respiratory symptoms;
- (5) Those who have visited the epidemic area and have not completed isolation for 14 days after returning to Hong Kong

#### **Criteria for inclusion in the test after exclusion**

- (1) If subjects quit in the middle of the trial due to their own wishes, but they wish to return to the clinical trial at certain time, we will investigate the subject again from the beginning of the trial.
- (2) Respiratory symptoms such as transient fever, dry cough, fatigue, runny nose and sore throat were excluded. Patients with the disappearance of respiratory symptoms after 14 days (excluding those with latent infection of COVID-19) can be re-included in this trial.

### **Information on the Trial Drug**

Treatment of administration, including product name, dosage, administration plan, administration route and treatment period. The detailed treatment in each group is shown below,

Table 1

Constitution of Chinese Medicine	Group	Formula

Deficiency of Qi and Yang: shortness of breath; Laziness, chilly limbs, self-perspiration, sore waist and knees; light tongue, thin white moss, deep and fine pulse	CM-induced invigorating of Qi and Yang (QYang-group)	Yu-Ping-Feng and Xiang-Sha-Liu-Jun formula (Nong's CM) <u>5g twice daily for each formula</u> <u>(20g in total per day)</u>
	Placebo control of invigorating Qi and Yang (PQYang-group)	The placebo is made of dextrin, bitterness agent, edible pigment, etc., and 5% herbal medicine of nourishing qi and yang <u>10g twice daily per placebo</u> <u>(20g in total per day)</u>
Deficiency of Qi and Yin: tiredness and weakness, shortness of breath when moving; fear of heat, five heart hot, self-perspiration and night sweat; red tongue, thin white or light peeling, weak and fast pulse	CM-induced invigorating of Qi and Yin (QYin-group)	Yu-Ping-Feng and Liu-Wei-Di-Huang formula (Nong's CM) <u>5g twice daily for each formula</u> <u>(20g in total per day)</u>
	Placebo control of invigorating Qi and Yin (PQYin-group)	The placebo is made of dextrin, bitterness agent, edible pigment, etc., and 5% herbal medicine for nourishing qi and yin <u>10g twice daily per placebo</u> <u>(20g in total per day)</u>

### Procedures and Protocol

The volunteers who completed the constitution judgment and met the inclusion criteria will receive COVID-19 preventive Chinese medicine (Table 1) and blood collection. The Chinese medicine formula is based on the body constitution of "deficiency of Qi and Yang" or "deficiency of Qi and Yin". The route of administration is oral. Included subjects will fill out the "Questionnaire of TCM symptom" and Fatigue scale at the beginning and end of the study. The production date with specific drugs will be marked on the bag. After 1-month treatment, the registered nurse will take 15ml of venous blood samples to investigate the changes of biochemical indicators. The corresponding prescriptions according to different constitution are shown in Table 1

Because we do not know if the Chinese medicine is effective for preventing COVID-19, we need the comparison. To do this, we will put participants into two Chinese medicine groups and two placebo group. The groups are selected by chance. Participants in one group will be given the Chinese medicine while participants in the other group will be given the placebo. It is important that neither you nor we know which of the two drugs you are given. This information will be in our files, but we will not look at these files until after the research is finished.

During the study, we will take blood from your arm at the beginning and ending of the experiment using a syringe and needle. Each time we will take about 15ml blood. At the end of the research, any left-over blood sample will be destroyed.

The healthcare workers will be looking after you and the other participants very carefully during the study. If we are concerned about what the drug is doing, we will find out which drug you are getting and make changes. If there is anything you are concerned about or that is bothering you about the research, please talk to me or one of the other researchers

### Description of the Process

#### Duration

The research will last for 1 month. During that time, it will be necessary for you to come to the clinic/hospital/health facility 2 days, for around 1 hours each day. We would like to make a phone call to you 3 months after your last clinic visit for a final check-up.

### **Side Effects**

3 Chinese formulas will be involved in this study, including Yu-Ping-Feng and Xiang-Sha-Liu-Jun formula (Nong's CM) and Liu-Wei-Di-Huang formula. It is possible that it may also cause some problems that we are not aware of. However, we will follow you closely and keep track of any unwanted effects or any problems. We may use some other medicines to decrease the symptoms of the side effects or reactions. Or we may stop the use of one or more drugs. Subjects with external self-perspiration, yin deficiency and night perspiration cannot use Yupingfeng formula, since it may aggravate the symptoms of sweating and yin deficiency. Subjects with dry mouth and tongue cannot use Xiangsha Liujun formula, because it may aggravate this symptom. Subjects without obvious kidney yin deficiency should not take Liuwei Dihuang formula, because it will cause diarrhea and loss of appetite.

### **Benefits**

If you participate in this research, you may have the following benefits: If subjects with deficiency of Qi and Yang and treated with Yu-Ping-Feng and Xiang-Sha-Liu-Jun formula (Nong's CM), the following symptoms will reduce: shortness of breath; Laziness, chilly limbs, self-perspiration, sore waist and knees; light tongue, thin white moss, deep and fine pulse. Whereas, if subjects with deficiency of Qi and Yin and treated with Yu-Ping-Feng and Liu-Wei-Di-Huang formula (Nong's CM), the following symptoms will reduce: tiredness and weakness, shortness of breath when moving; fear of heat, five heart hot, self-perspiration and night sweat; red tongue, thin white or light peeling, weak and fast pulse. Of note, there may not be any benefit for you but your participation is likely to help us find the answer to the research question. There may not be any benefit to the society at this stage of the research, but future generations are likely to benefit

### **Reimbursements**

We will give you 100 HKD to pay for your travel expenses to the clinic. You will not be given any other money or gifts to take part in this research.

### **Confidentiality**

It is possible that if others in the community are aware that you are participating, they may ask you questions. We will not share the information of those individuals participated in the research. The information that we collect from this research project will be kept confidential. Information about you that will be collected during the research will be put away and no-one but the researchers will be able to see it. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is and we will lock that information up with a lock and key. It will not be shared with or given to anyone except research sponsors and your clinician

### **Sharing the Results**

The knowledge that we get from doing this research will be shared with you through phone or face-to-face meeting before it is made widely available to the public. Confidential information will not be shared. we will publish the results in order that other interested people may learn from our research

**Right to Refuse or Withdraw**

You may stop participating in the research at any time that you wish without losing any of your rights as a patient here. Your treatment at this clinic will not be affected in any way

**Who to contact**

If you have any questions you may ask us now or later, even after the study has started. If you wish to ask questions later, you may contact the following person: Zhang Cheng; Tel: 9202 2545.

**PART II: Certificate of Consent**

**I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.**

**Print Name of Participant** \_\_\_\_\_

**Signature of Participant** \_\_\_\_\_

**Date** \_\_\_\_\_  
**Day/month/year**

**Statement by the researcher/person taking consent**

**I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the following will be done:**

- 1: This study will be carried out in accordance with the procedures and agreements involved in this informed consent.
- 2: During this study, the researchers will keep in touch with the participants and solve any questions they ask in a timely manner.

**I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant has been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.**

**A copy of this ICF has been provided to the participant.**

**Name of Researcher/person taking the consent** \_\_\_\_\_

**Signature of Researcher /person taking the consent** \_\_\_\_\_

**Date** \_\_\_\_\_  
**Day/month/year**