

## **Participant Information Sheet – Medical (Extended)**

**Project Title:** Community-based cardiac rehabilitation program for Chinese migrants in Australia: A pilot randomised controlled trial

### **Project Summary:**

You are invited to participate in a research study on cardiac rehabilitation (CR) being conducted by researchers from Western Sydney University, Macquarie University, and the University of Sydney. The objectives of this pilot study are to (1) evaluate the acceptance and feasibility of the co-designed community-based CR program for Chinese migrants in Australia, and (2) explore the effectiveness and cost effectiveness of the co-designed CR program in increasing the accessibility, participation, adherence, and completion rate among cardiac patients from Chinese migrants in Australia. The participation from Chinese migrants will help us understand the feasibility and value of doing a larger study that will assess the effectiveness of this CR program.

The researchers involved with this project are Dr. Guoyan Yang, Professor Dennis Chang, Dr. Carolyn Ee, Dr. Mike Armour, all from the NICM Health Research Institute of Western Sydney University, Australia, Professor Hosen Kiat from Macquarie University, Australia, and Professor Clara Chow from the University of Sydney, Australia.

This research project has been approved by the Western Sydney University Ethics Committee (H15154).

### **How is the study being paid for?**

This study is funded by a Western Sydney University Research Support Program Fellowship start-up fund.

### **What will I be asked to do?**

You are invited to take part in this study if you meet the following criteria:

- Aged  $\geq$  18 years old.
- Are an Australian citizen or permanent resident.

- Are of Chinese ancestry, speak Mandarin or Cantonese at home, and can read Chinese (simplified or traditional).
- Experienced at least one of the following conditions or events:
  - myocardial infarction,
  - heart failure, or
  - coronary artery diseases with recent revascularisation with coronary artery bypass graft (CABG) or coronary angioplasty/stenting.
- Have been referred to attend a cardiac rehabilitation program by a medical doctor, no matter whether attended a cardiac rehabilitation program in the past.
- Being discharged home for at least 12 weeks.
- Are willing and able to give written informed consent.
- Have a mobile phone and the capacity to receive and understand text messages.
- Have access to the internet.

After you are completing an online self-screen survey or responding to a call of interest, you will be contacted via phone call by an investigator within 3 working days to confirm if you are eligible to take part in this study or not.

If you are eligible to participate in the study, you will be invited to discuss the study further, give written consent to take part in this study, and be put into one of the two groups. You will have an equal chance (50:50) of being put in either the intervention group or waitlist control group that is completely random and determined by a computer-generated sequence.

#### **What happens in the intervention group?**

If you are allocated to the intervention group, you will be given a community-based cardiac rehabilitation program for 24 weeks. This program is co-designed by our research team, health care practitioners, Tai Chi instructors and patients from Chinese migrants, including health education via text messages, programmed Shared Medical Appointment, and online live Tai Chi class:

- You will receive 4 text messages per week (Monday to Friday between 9am to 5pm) for 24 weeks. The text message is semi-personalised, in simplified Chinese and traditional Chinese, covering contents on general cardiac rehabilitation knowledge, diet/nutrition, physical activity, medication adherence, psychosocial management, and smoking cessation.
- You will be asked to attend a Shared Medical Appointment (SMA) group visit session in the start of this study. The SMA group session lasts 90 min, involving 6-12

patients, a facilitator, a cardiologist, a nurse, a dietitian, and an exercise therapist. In the SMA, you can consult the cardiologist consecutively 5-8 min at a time per individual consultation during the first 60 min, followed by 30 mins of structured education delivered by a dietitian and an exercise therapist in a group setting. All participants of the SMA will be asked to sign a confidentiality agreement to protect health privacy of attendees before the commencement of SMA. In addition, you will have additional three one-on-one consultations with the nurse and allied health practitioners outside of the SMA group session. The one-on-one consultation lasts 15 min to 30 min. All sessions will be held on Weekdays at 6pm (UTC+11) via zoom meetings. The sessions will be delivered in Mandarin (with Cantonese translation if necessary).

- You will be asked to attend online live Tai Chi class, twice per week, for 24 weeks. The class will be held on Tuesday and Thursday at 8am (UTC+11) via zoom meetings. Each class lasts 60 min. The contents include walking, standing posture, cloud hands and 6-form Chen-style Tai Chi. Class attendance will be recorded by the Tai Chi instructor in each class and reasons for missed sessions will be tracked by phone. You are encouraged to practice at least three days outside of group class at home and record your home practice in a participant diary.

#### **What happens in the waitlist control group?**

If you are allocated to the waitlist control group, you will be encouraged to keep the normal lifestyle and physical activity. You will receive 2 text messages only – a welcome message after group allocation and an exit message at the conclusion of the study. No WeChat group will be set up for the waitlist control group. No other interventions will be given during their wait period. You will receive the same CR program after your wait period for free.

#### **What tests will I be asked to do?**

No matter which group you are in, you will be asked to provide demographic information and medical history at baseline, and have the same tests below during the study:

- You will be provided with electronic referral letter by researchers to test your blood sugar and your cholesterol levels at your local Lavery Pathology in the beginning, middle (12 weeks) and end of this study (24 weeks).
- You will be asked to complete some questionnaires about your health, including quality of life, self-efficacy, social support, stress, anxiety and depression, in the beginning, middle and end of this study.

- You will receive a set of telemonitoring kit to monitor your risk factors (including weight, blood pressure, heart rate, and blood oxygen levels) at home in the beginning, middle and end of this study. A wireless telemonitoring kit including an iHealth Connected Blood Pressure Monitor, an iHealth Lite Wireless Scale, and an iHealth wireless PO3M pulse oximeter, will be delivered to you by Australian Post, with a printed user manual in simplified and traditional Chinese. The manual includes how to use the iHealth application to sync your results to iHealth Cloud Database and how to use the devices provided. Training sessions will be provided to you via Zoom meeting by a research assistant at each timepoint for outcome measurement to ensure you know how to use the iHealth application and the devices. You can read the outcomes from the devices for self-monitoring.
- You will also be asked to wear a physical activity tracker for 7 days to measure the distance and steps you walked in the beginning, middle and end of this study. An activity tracker (FitBit Inspire 2 fitness tracker and heart rate tracker) will be delivered to you by Australian Post, with a printed user manual in simplified and traditional Chinese. Instruction sessions will be provided to you via Zoom meetings by a research assistant at each timepoint for outcome measurement to ensure you know how to use the devices and read the outcomes.
- You will be invited to take part in an exit interview when you complete the study to share your experience of the study procedure and your satisfaction of the cardiac rehabilitation program. The one-on-one interview will last around 30 minutes.
- You will be asked to test your exercise capacity by the 6-minute walking test (6MWT), which is the distance covered over a time of 6 minutes. Training sessions will be provided to you via Zoom meeting by a research assistant at each timepoint for outcome measurement to ensure you and your carers/helpers who will assist the 6MWT know how to use the equipment and read the results.
- You will also be asked to record your returning to work and driving if applicable, and time after your heart event, in a provided diary. You will be asked to record your weekly medication adherence, diet, smoking, and home practice of Tai Chi in your diary, as well as readmission, cardiac events, or adverse events, if applicable, during the study.

### **How much of my time will I need to give?**

If you are allocated to the intervention group, the overall total time you need to attend the cardiac rehabilitation program is 50.5 to 51.5 hours: (1) You will read 4 text messages per week for 24 weeks. Each message will take around 10 seconds to 40 seconds to read; (2)

You will attend one Shared Medical Appointment group session and three one-on-one consultation session, which takes approximately 2 to 3 hours; (3) You will attend online live Tai Chi class two times per week for 24 weeks, lasting 60 minutes per session. In addition, you are also encouraged to have home practice of Tai Chi outside of the class at least three times per week. This may take around 10 minutes to one hour daily depending on your preference.

If you are allocated to the waitlist control group, you will be offered the same cardiac rehabilitation program after your 24 weeks of waiting period. It will take a total of 50.5 to 51.5 hours to complete the program. In addition, you will be encouraged to have home practice of Tai Chi outside of the class at least three times per week. This may take around 10 minutes to one hour daily depending on your preference.

Additionally, no matter which group you are in, you will need up to 5 hours in total to complete all the tests listed under “What tests will I be asked to do?” from the beginning to the end of the study.

### **What benefits will I, and/or the broader community, receive for participating?**

The study aims to further medical knowledge and may improve future cardiac rehabilitation for Chinese migrants in Australia. This study may lead to future larger studies which will evaluate the effectiveness and cost effectiveness of this co-designed community-based cardiac rehabilitation program. The results may have significant benefits for improving lives of Chinese migrants and people from the broader community who have cardiovascular diseases.

Through taking part in this study, you may benefit directly from the chance to (1) receive the health education via text messages, (2) interact and share common experiences with other Chinese migrants in Australia in the Shared Medical Appointment, learn from other people’s experiences and consult your health with cardiologist, cardiac nurse, and allied health practitioners, and (3) attend online live Tai Chi class that you can continue use as a self-care method in your daily life.

You will get some monitoring of your cardiovascular risk factors using wireless devices and blood tests. Your GP will be notified if necessary and with your written consent to help you better manage your cardiac health.

### **Will the study involve any risk or discomfort for me? If so, what will be done to rectify it?**

We do not foresee any anticipated significant risks to you from participating in this study. If you are allocated to the intervention group, you will be provided a cardiac rehabilitation program, including health education, Shared Medical Appointment (SMA), and online live Tai Chi. Taking part in this study means that you will have to give up some of your time to attend the SMA and online live Tai Chi classes. If you have difficulties in using zoom meetings, you will be provided trainings and IT support before the start of each session. All the online sessions will be held after regular business hours. You are also encouraged to get IT support from your younger family members.

Some people may feel uncomfortable or embarrassing to have health consultation in a group setting. If you are concerned about this, please speak to our investigator, as this type of SMA program may not be suitable for you. Your privacy and confidentiality will always be respected. Confidentiality agreement will be signed by all participants of the SMA group session. However, there will still be risk of health privacy and confidentiality as the SMA is in a group setting. You do not need to share anything if you do not wish. The SMA group sessions will be facilitated by experienced and qualified facilitators.

You might feel uncomfortable pain during and after Tai Chi practice depending on their physical capacity. This could include minor muscle soreness. These risks will be mitigated by the following strategies: (1) the Tai Chi intervention is co-designed by the research team, experienced Tai Chi masters, clinicians, and patients, to address patients' physical capacity, needs, and barriers; (2) the online live Tai Chi class will be led by an experienced Tai Chi instructor with over 15 years of experience, who will give Tai Chi instruction and discuss safety practice tips with you during each class; (3) you will be allowed to practice in your own pace and your movements will be modified by the instructor if you have limitations of exercise such as poor balance or joint problems; (4) you will be asked to have a chair nearby and can have a rest when necessary during the class; (5) before the class you will be provided with training about safe practice, recognising warning signs of cardiac events, and improving internet technology literacy; (6) the Tai Chi instructor and teaching assistants will pay close attention to your safety, and your practice will be under close supervision during the class.

You will be encouraged to practice at least three times outside of the group class in an adequately spacious and safe place (a flat space at least 2 square meters, with minimal obstacles) at your place. Since home practice is not under the supervision of the Tai Chi instructors and the teaching assistants, there are potential risks for you including increased falls risks, and risk of joint or muscle pain if practices are not done appropriately. These risks

will be mitigated by the following strategies: (1) you will be asked to do home practice using the skills learned in the class and particularly safety practice skills; (2) you will be asked to inform the locations where you plan to do home practice to your Tai Chi instructor to ensure the space are safe to practice Tai Chi at home; (3) you are encouraged to practice at the same place at home where you attend the online live class, to ensure the safety of space has been checked by the Tai Chi instructor during the class; (4) you are encouraged to have a carer or helper nearby when do Tai Chi practice at home; (5) a WeChat group will be set up for participants in the intervention group to increase your social support and ensure timely feedback from the Tai Chi instructor and the teaching assistants to support your home practice.

No matter which groups you are in, you will be asked to have a fasting blood test at your local Lavery Pathology to check your sugar control and cholesterol levels in the start, middle and end of the study. Blood tests are usually well tolerated. However, some people may experience minor pain or discomfort, and bleeding or bruising, and some people might feel mild dizziness while fasting. However, the Lavery Pathology has professional trained nurses to take blood samples, which would minimise your risk of uncomfortable feelings. Your local Lavery will create a unique digital medical record for you once receives a request to provide pathology services for you. Your Name, address, gender, and data of birth information will be retained by Lavery. Every time Lavery performs a pathology service for you, new information will be added to your medical record. Lavery takes reasonable steps to protect patient medical records from misuse, interference, and loss, and from unauthorised access, modification, and disclosure. These steps include ensuring that their information technology systems and processes comply with the requirements of the *National Pathology Accreditation Advisory Council* for information communication. Lavery must generally retain health information about an individual:

- for 7 years from the last occasion on which Lavery provided a health service to the individual – if the information was collected when the individual was 18 years old or older; or
- until the individual turns 25 – if the information was collected when the individual was less than 18 years old.

Lavery Pathology's privacy policy is available at: <https://www.lavery.com.au/privacy/>.

You will be asked to do a low-risk test, 6-minute walking test (6MWT) that measures how far you can walk in 6 minutes. You may feel uncomfortable because of the test, due to risks of elevated blood pressure, low oxygen levels, or breathlessness. These risks can be mitigated by the following strategies: (1) you will be asked a have a carer/helper to help you do the

6MWT; (2) you will be provided an online training about how to do the test appropriately; (3) the carer/helper will set up a clear sight with a web-camera along length of the track for a research assistant to observe the measurement and monitor your risks remotely; (4) your blood pressure, oxygen level, heart rate, and breathlessness will be measured before and after the 6MWT, and be monitored during the measurement.

You will be required to record any adverse events (AEs) weekly in the participant diary. All reported AEs that occur between consent and the last visit for the study will be collected once a week and assessed within 48 hours. You will also be encouraged to spontaneously report any AEs to the research team outside of the weekly collection period should you have any concerns.

### **How do you intend to publish or disseminate the results?**

It is anticipated that the results of this research project will be published in journal articles and presented in a variety of academic conferences and other scientific meetings. In any publication and/or presentation, information will be provided in such a way that the participant cannot be identified, except with your permission.

### **Will the data and information that I have provided be disposed of?**

Please be assured that only the researchers will have access to the raw data you provide. However, your data may be used in other related projects for an extended period of time, such as larger randomised control trials. Please note that the minimum retention period for data collection is five years post-publication, but data may be kept for up to 15 years to allow other researchers access to this data. The data and information you have provided will be securely disposed of after this time.

### **Can I withdraw from the study?**

Participation is entirely voluntary, and you are not obliged to be involved. If you do participate you can withdraw at any time without giving reason. Whatever your decision, it will not affect your medical treatment or your relationship with the medical staff.

### **Can I tell other people about the study?**

Yes, we encourage you to tell other people about the study by providing them with Dr. Guoyan Yang's contact details. They can then contact Dr. Yang to discuss their participation in the research project and obtain a copy of the participant information sheet.

### **What if I require further information?**



Please contact Dr. Guoyan Yang should you wish to discuss the research further before deciding whether or not to participate in the research.

Dr. Guoyan Yang, Research Support Program Fellow, NICM Health Research Institute, Western Sydney University, email: [e.yang@westernsydney.edu.au](mailto:e.yang@westernsydney.edu.au)

### **What if I have a complaint?**

If you have any complaints or reservations about the ethical conduct of this research, you may contact the Ethics Committee through Research Engagement, Development and Innovation (REDI) on Tel +61 2 4736 0229 or email [humanethics@westernsydney.edu.au](mailto:humanethics@westernsydney.edu.au).

Any issues you raise will be treated in confidence and investigated fully, and you will be informed of the outcome.

If you agree to participate in this study, you may be asked to sign the Participant Consent Form. The information sheet is for you to keep and the consent form is retained by the researcher/s.

This study has been approved by the Western Sydney University Human Research Ethics Committee. The Approval number is H15154.

### **What will happen with my information if I agree to it being used in projects other than this one?**

Thank you for considering being a participant in a University research project. The researchers are asking that you agree to supply your information (data) for use in this project and to also agree to allow the data to potentially be used in future research projects.

This request is in line with current University and government policy that encourages the re-use of data once it has been collected. Collecting information for research can be an inconvenience or burden for participants and has significant costs associated with it. Sharing your data with other researchers gives potential for others to reflect on the data and its findings, to re-use it with new insight, and increase understanding in this research area.

You have been asked to agree to Extended consent.

### **Extended consent**

When you agree to extended consent, it means that you agree that your data, as part of a larger dataset (the information collected for this project) can be re-used in projects that are

- an extension of this project
- closely related to this project
- in the same general area of this research.

The researchers will allow this data to be used by a clinical trial evaluating the effectiveness and cost effectiveness of the co-designed cardiac rehabilitation program for Chinese migrants in Australia.

To enable this re-use, your data will be held at the University in its data repository and managed under a Data Management Plan. The stored data available for re-use will not have information in it that makes you identifiable. The re-use of the data will only be allowed after an ethics committee has agreed that the new use of the data meets the requirements of ethics review.

The researchers want to keep the data for 15 years for possible re-use. After this time the data will be securely destroyed.

You are welcome to discuss these issues further with the researchers before deciding if you agree. You can also find more information about the re-use of data in research in the [National Statement on Ethical Conduct in Human Research](#) – see Sections 2.2.14 - 2.2.18.

<https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018>