

# **LONG-TERM EFFECTS OF TAI CHI ON EXERCISE CAPACITY AND QUALITY OF LIFE IN CHRONIC OBSTRUCTIVE PULMONARY DISEASE: A PILOT STUDY**

## **INFORMATION FOR PARTICIPANTS**

### **INVESTIGATORS:**

Dr Zoe McKeough: Physiotherapist at The University of Sydney, NSW;

Professor Jennifer Alison: Professor of Respiratory Physiotherapy, The University of Sydney and Sydney Local Health District, NSW;

Dr Regina Leung: Physiotherapist at Concord Repatriation General Hospital NSW;

Ms Sally Wootton: Physiotherapist at Chronic Disease Community Rehabilitation Service, Northern Sydney Local Health District, NSW;

Dr Lei Fang: Research Fellow at The University of Sydney, NSW.

**PROJECT SPONSOR:** The University of Sydney (Bridging Support Grant)

### **INTRODUCTION:**

You are invited to take part in a research study that will investigate the effectiveness of a Tai Chi program on exercise capacity and quality of life in people with chronic obstructive pulmonary disease (COPD). This Participant Information Sheet will tell you about what is involved in the study and help you decide whether or not you wish to take part. Please read this information carefully. If there is anything you do not understand or if you feel you need more information about anything, please ask. Before you make a decision, please feel free to talk things over with a relative, a friend or your own doctor.

### **WHY HAVE I BEEN ASKED TO TAKE PART?**

You have been invited to take part in this research because you suffer from COPD and you have indicated that you are willing to participate in an exercise training program.

### **WHAT IS THE PURPOSE OF THIS RESEARCH?**

Exercise training, using exercise equipment such as stationary bikes and treadmills, has been shown to help people with COPD. However, not everyone has access to programs that use such equipment and such equipment is not usually available at home for continued exercise training in the long-term. Tai Chi, a gentle exercise, may provide an alternative form of exercise training which has shown benefits after an 8-12 week program. However, the effect of continuing to use Tai Chi at home after completion of an initial Tai Chi program remains unknown. This study aims to investigate the effects on exercise capacity and quality of life of a short-term (8-week) supervised Tai Chi training program followed by continuation of unsupervised Tai Chi at home for 6 months, in people with COPD.

### **DO I HAVE TO TAKE PART IN THE STUDY?**

Taking part in any research is entirely voluntary. If you do decide to take part you can withdraw at any time without having to give a reason. Please be assured that, whatever your decision, it will not affect your routine treatment, your relationship with those treating

you or your relationship with the chronic disease community rehabilitation service, Mona Vale Community Health Centre.

### **WHAT WILL HAPPEN TO ME IF I TAKE PART?**

If you agree to participate in this study, you will be required to attend two days of testing at each of the following time points: 1) the beginning; 2) end of the 8-week supervised Tai Chi program; 3) three months into the maintenance Tai Chi program; and 4) six months into the maintenance Tai Chi program which will be the end of the study. Each testing day should take approximately one and a half hours. The testing will be held at the Mona Vale Community Health Centre.

The following measures will be taken:

- 1) Lung function. For this you will be asked to blow into a spirometer machine to measure how much air your lungs are able to blow out.
- 2) Exercise capacity: For this you will perform two six-minute walk tests on two separate days. For the walk tests you will be asked to walk for six minutes and can rest if you need to.
- 3) Balance: You will be asked to perform a series of balance tests which include tests for your hip strength, ability to reach forward without losing balance, ability to stand on one leg, compensatory ability when your balance is being challenged, ability to stand on an uneven surface and ability to stand up from a chair and walk quickly.
- 4) Quality of life: For this you will be asked to fill in a questionnaire. This will take about 15 minutes to complete and it will be done during your rest period between the other tests.
- 5) Physical activity: For this you will be asked to wear a device called the SenseWear Armband. This armband will need to be worn for 24 hours per day for seven days at home and only be removed for showering. The armband should not cause any discomfort and can be loosened or removed if any discomfort occurs. You will be required to return the armband at the end of the seven days when you start your Tai Chi program.
- 6) Compliance of home practice: For this you will fill in a diary. Record the length of each home Tai Chi practice session (in minutes) on the every practice day.
- 7) Tai Chi training feedback: You will be asked to complete a survey. This will take about 15 minutes to complete and will be done at the final assessment session (at the six month follow up assessment session).

### **Tai Chi Training**

On completion of the testing at the beginning of the study, you will then be asked to participate in the Tai Chi training. For the first eight weeks, you will be asked to attend your rehabilitation centre at Mona Vale Community Health Centre where you will be trained with the Sun-style Tai Chi program. You will be asked to attend this supervised program twice weekly for approximately 60 minutes each time. You will also be asked to practice Tai Chi at home on the five remaining days. A Tai Chi booklet and a Tai Chi video/compact disc will be provided for home training.

Following completion of the eight week supervised program, you will be asked to continue Tai Chi as an unsupervised maintenance program five times per week in your own home for a further six months. The Tai Chi booklet and Tai Chi video/compact disc will continue to be

provided for this home training which you will perform at the same intensity as your supervised program. Strategies to progress this home training will be discussed with you at the end of the supervised program. You will also be asked to attend monthly “booster” sessions of supervised Tai Chi training during this six-month period. There will be six one-hour “booster” sessions in total. The purpose of these “booster” sessions is to provide you with support and feedback to assist you with your home training.

### **WHAT ARE THE ALTERNATIVES TO PARTICIPATION?**

Participation in this study is entirely voluntary. You do not have to take part in it. If you do take part, you can withdraw at any time without having to give a reason. Whatever your decision, please be assured that it will not affect your medical treatment or your relationship with the staff who are caring for you. If you do not wish to take part you will continue with your standard treatment of pulmonary rehabilitation. You can discuss your options with the rehabilitation physiotherapist before deciding whether or not to take part in the study.

### **WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART?**

While we intend that this research study further medical knowledge and may improve treatment of COPD in the future, there is a possibility that the direct benefits to you may not be great. However, the tests of exercise tolerance will allow us to compare your results to those of a similar aged person without lung disease.

### **WHAT ARE THE RISKS OF TAKING PART?**

Medical treatments often cause side-effects. You may have all, some or none of the side-effects stated below and they may be mild, moderate or severe. If you have any of these side-effects or you are worried about them, please talk to your physiotherapist. They will also be looking out for any side-effects and will discuss with you the best way of managing any that do occur. Many side-effects go away shortly after treatment ends. However, some can be serious, long-lasting or permanent. If a severe side-effect or reaction occurs, your physiotherapist may need to stop your participation in the study.

There is a slight possibility of an adverse reaction during the measurement of exercise capacity, although it is extremely unlikely that any unforeseen cardiac events would occur. Your heart rate and oxygen saturation will be monitored by a sensor attached to your finger. All exercise tests will be terminated if you request it or if the researchers decide this is necessary for your well-being. None of the attachments should cause you any discomfort. There is a slight possibility of an adverse reaction to the Tai Chi exercise although this is likely to be minimal. You may feel a little tired after training which should not last long.

### **CONFIDENTIALITY**

If you consent to take part in this study your hospital medical records may be inspected by the researchers, by regulatory authorities or by the Human Research Ethics Committee. By signing the consent form you are giving permission for this to be done. All details obtained by those named will remain confidential. A report of this study may be submitted for publication but individual participants will not be identifiable.

### **COMPENSATION**

If you suffer any injuries or complications as a result of this study, you should contact Ms Sally Wootton as soon as possible. They will assist you in arranging appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

You do not give up any legal rights to compensation by participating in this study.

### **FURTHER INFORMATION**

When you have read this information, Ms Sally Wootton will discuss it with you further and answer any questions you may have. If you would like to know more at any stage, please feel free to contact Dr Zoe McKeough, Physiotherapist at the University of Sydney on (02) 9515 9269. This information sheet is for you to keep.

This study has been approved by the Human Research Ethics Committee – Concord Repatriation General Hospital of the Sydney Local Health District. If you have any concerns or complaints about the conduct of the research study, you may contact the Executive Officer of the Ethics Committee, on (02) 9767 5622.

The conduct of this study at the Mona Vale Community Health Centre has been authorised by the Northern Sydney Local Health District. Any person with concerns or complaints about the conduct of this study may also contact the Research Governance Officer on (02) 9926 4588 and quote protocol number (HREC/16/CRGH/18).

**Contact persons:** Ms Sally Wootton: (02) 9887 5676; Dr Zoe McKeough: (02) 9351 9269; Prof Jennifer Alison: (02) 9351 9371; Dr Regina Leung (02) 9767 7602