

CONSENT TO PARTICIPATE IN RESEARCH

Effect of a Walking Program and Inspiratory Muscle Training on Individuals with Chronic Heart Failure – a Pilot Study

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You are asked to participate in a research study conducted by Dr. Suh-Jen Lin from the School of Physical Therapy at the Institute of Health Sciences – Dallas, Texas Woman's University. This project is being completed as part of a faculty study project. Your participation in this study is entirely voluntary; you can quit at any time. Please read the information below and ask questions about anything you do not understand, before deciding whether or not to participate.

PURPOSE OF THE STUDY

To explore the effect of exercise training on shortness of breath and endurance of the heart, and to examine the additional benefits of breathing muscle training on physical activity, breathing muscle strength, heart rate response, walking speed, and quality of life.

PROCEDURES

If you volunteer to participate in this study, you will be asked to do the following things: Participate in initial tests consisting of a 6-minute walk test, breathing muscle strength testing, comfortable walking test, grip strength test, single limb stance test, and quality of life survey. During the walk test, you will be put on a finger oximeter to monitor your heart rate and oxygen saturation throughout the test. You will also be asked basic information about your health, age, height, and weight. At the end of test session, you will be given a pedometer to wear and to record the number of steps you take each day. You are required to record your steps in a daily log. You will also be provided a unit of accelerometer (a delicate unit of pedometer) to monitor your steps duration for the first week and the 6th week. You will need to return this accelerometer to us at the end of recording. The initial session at our site will last for about two hours.

You will be asked to participate in a daily walking program and breathing muscle training program. The breathing exercise is about 15 minutes a day. The walking program is to accumulate about 40-45 minutes of walking a day. You can begin with short 15 minutes of walking twice a day; then gradually increase your walking routine as your capacity improves. For the weekly follow up (about 15 minutes), you need to come to our site to re-assess your inspiratory muscle strength and to turn in your weekly pedometer log. If you have transportation issue, we will try to conduct the weekly reassessment at your home if time and scheduling are allowed. Then, the researcher will reset you training target step count and target breathing intensity of the following week. At the end of six weeks, you will return to our site for a 2-hr visit to repeat the tests done during week one.

Approved by the
Texas Woman's University
Institutional Review Board
Approved: March 14, 2017

_____(initials)
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POTENTIAL RISKS

It is possible to experience fatigue and overexertion during this study. This risk will be managed by taking rest breaks as needed. Another risk is the loss of confidentiality. This will be managed by giving each participant an unidentifiable code. All data will be stored in a locked filing cabinet in a locked research room, and data will be destroyed upon completion of this study. The researchers will try to prevent any problem that could happen because of this research. You should let the researchers know at once if there is a problem and they will help you. However, TWU does not provide medical services or financial assistance for injuries that might happen because you are taking part in this research.

POTENTIAL BENEFITS TO SUBJECTS

You will benefit from the free access to the breathing muscle training equipment and instruction on proper use. You will also benefit from the effects of exercise due to the daily walking program. A free pedometer and a heart rate monitor will also be provided for you to keep. You will be provided with \$50 for your participation in the study.

CONFIDENTIALITY

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. Confidentiality will be maintained by means of coding each participant with a unique, unidentifiable number. Data will be kept in a locking filing cabinet within a locked room in the research facility, and only the research team will have access to it. All data and electronic data will be destroyed upon completion of this study.

PARTICIPATION AND WITHDRAWAL

You can choose whether or not to be in this study. If you volunteer to be in this study, you may withdraw at any time without consequences of any kind or loss of benefits to which you are otherwise given. You may also refuse to answer any questions you do not want to answer.

RIGHTS OF RESEARCH SUBJECTS

You will be given a copy of this signed and dated consent form to keep. If you have any questions about this research, you can ask researchers. Their phone numbers are at the top of this form. If you have any questions about your rights in this research, or the way the research has been conducted, please contact the Texas Woman's University Office of Research & Sponsored Programs at (940) 898-3378 or email irb@twu.edu. I understand the procedures described above. My questions have been answered to my satisfaction, and I agree to participate in this study. I have been given a copy of this form.

Printed Name of Subject

Signature of the Subjects

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