

## **Cover Page**

**Official Title of the study:** Effect of Aerobic Interval Training Versus Resistance Interval Training on Ejection Fraction in Post Stable Myocardial Infarction Patients

**ClinicalTrials.gov Identifier:** NCT03708484

**Date of the document:** July 15, 2016

### **INFORMED CONSENT FORM**

Thank you very much for agreeing to participate in this research study titled “Effectiveness of aerobic interval training verses resistance interval training in post- myocardial infarction patients”. The purpose and nature of the study has been explained to you. The study means no potential harm to any participant. The information provided by you in this questionnaire will be used for research purposes only. Anonymity will be ensured and your identity will be kept confidential and will not be disclosed to anyone. You are free to withdraw from the study any time. Your signature will ensure that you have understood the terms and nature of the study and your queries have been answered.

#### **Explanation Of Outpatient Cardiac Rehabilitation Program:**

You will be placed in a program that will include physical exercises, educational activities, and other health related services. The levels of exercise, that you will undertake, will be based on your cardiovascular response to an exercise test and other clinical information. You will be given clear instructions regarding the amount and kind of regular exercise you should do. Depending on your progress, your exercise sessions maybe adjusted.

#### **Importance of Cardiac Rehabilitation:**

Cardiac rehabilitation is coordinated, multifaceted interventions designed to optimize a cardiac patient's physical, psychological, and social functioning.

- Prevents from surgical intervention options along with its associated risks and discomforts
- Limits the risk for re-infarction or sudden death
- Reduces Readmissions.
- Relieve cardiac symptoms (lessening of chest pain, dyspnea and fatigue) and reduces the need for medicines to treat heart or chest pain.
- Improve exercise tolerance, functional capacity, and decreases myocardial oxygen demand at any level of physical activity.
- Improves quality of life by reducing Risk factors and psychological well being
- Reintegrate MI patients into successful functional status in their families and in society.

#### **Monitoring:**

The cardiac rehab doctor will monitor your blood pressure, heart rate, body weight, and other signs and symptoms related to your condition. You agree to report to the rehab staff any unusual, new, or worsened symptoms associated with your exercise program. These include but are not limited to unusual shortness of breath with low level activity, pain, pressure, tightness, heaviness in the neck, chest, jaw, back and/or arms, unusual fatigue with exercise, unusually fast, slow, or irregular heart rate, faintness or dizziness.

**Participation Risks and Discomforts:**

There exists the possibility of certain changes occurring during exercise sessions. These include abnormal blood pressure, fainting, irregular, fast or slow heart rhythm, and in rare instances, heart attack, stroke, or death. Every effort will be made to minimize those risks by provision of appropriate supervision during exercise. Emergency equipment and trained personnel are available to deal with unusual situations that may arise.

**Benefits to be expected:**

Participation in the cardiac rehab program may help to evaluate which activities you may safely engage in during your daily life. No assurance can be given that cardiac rehab will increase your exercise tolerance, but considerable evidence indicates improvement is usually achieved.

**Responsibility of the Participant:**

To promote your safety and gain benefit, you must give priority to regular attendance and adherence to the prescribed intensity, duration, frequency, progression and type of activity. To achieve the best possible care:

**DO NOT**

- Withhold any information pertinent to symptoms from any rehab member.
- Exceed your target heart rate.
- Exercise when you do not feel well or are physically ill.
- Exercise within 2 hours of using tobacco products.
- Use extremely hot water during showering after exercise (avoid sauna, steam bath, and similar extreme temperatures).

**DO**

- Report any unusual symptoms that you experience before, during, or after exercise.
- Follow recommendations made by cardiac rehab staff concerning the limits on any exercise, or health-related activities that you may be encouraged to do.

**Use of Medical Records:**

The information that is obtained while you are a participant in cardiac rehabilitation will be treated as privileged and confidential. Your medical records will not be released or reviewed by any person except your referring physician without your written consent. The information obtained, however, may be used for statistical analysis or scientific purposes with your right to privacy retained.

**Inquiries:**

Any questions about the cardiac rehabilitation program are welcome. If you have any doubts or questions, please ask us for further explanation.

**Freedom of Consent:**

I agree to voluntarily participate in the cardiac rehabilitation program. I understand that I am free to deny any consent if I so desire, both now and at any point in the program.

I acknowledge that I have read this form in its entirety or it has been read to me and I understand my responsibility in the cardiac rehabilitation program. I accept the risks, rules, and regulations set forth.

Knowing these, and having had an opportunity to ask any questions I may have had which were answered to my satisfaction, I consent to participate in the Cardiac Rehabilitation program at Railway General Hospital.

Signature of Patient: \_\_\_\_\_

Date: \_\_\_\_\_

Signature of Therapist \_\_\_\_\_

Date: \_\_\_\_\_