

HF-ACTION
Manual of Operations – Cardiac Rehabilitation

1. Cardiac Rehabilitation Overview

1.1 Background

One of the hallmarks of heart failure is exercise intolerance. While central hemodynamic abnormalities certainly contribute to this exercise intolerance, heart failure patients also have significant skeletal muscular abnormalities similar to that seen in deconditioning. Previous smaller studies have shown that heart failure patients have improved quality of life and exercise capacity after cardiac rehabilitation, without adverse cardiac effects. However, the effects of exercise training on heart failure morbidity and mortality is unknown at this time. HF-ACTION (Heart Failure - A Controlled Trial Investigating Outcomes of Exercise TraiNing), is a multicenter randomized trial of exercise training involving 3,000 patients with New York Heart Association (NYHA) class II-IV heart failure. The primary objective of this study is to examine the effects of exercise training (both supervised and unsupervised) on hospitalization and mortality in heart failure, as compared with patients receiving standard heart failure care. In addition, HF-ACTION will examine the effects of exercise training on secondary endpoints, including submaximal and maximal exercise capacity, quality of care, health care utilization and mood disorders. This study will enroll 3,000 NYHA class II-IV patients in 41 centers across the United States and Canada with a left ventricular ejection fraction of $\leq 35\%$. These patients will be randomized in a 1:1 fashion to exercise training plus usual medical care, versus usual medical care alone. Those patients randomized to exercise training will undergo 36 supervised sessions of exercise training, followed by an in-home exercise program. Patients will return to the cardiac rehabilitation program periodically for exercise training. This document outlines the procedures for the supervised exercise training portion of the HF-ACTION study.

1.2 Obtaining consent for enrollment in rehabilitation

All participants referred for cardiac rehabilitation as part of the HF-ACTION study has been previously consented by the Principal Investigator at _____ (thereafter referred to as the Study Center). These participants demonstrate an understanding of the purpose and procedures associated with the HF-ACTION study, including that of the supervised and unsupervised exercise training portion of this study.

1.3 Overview of exercise training

Cardiac rehabilitation is comprised of the following components:

a. Initial Evaluation and Goal Setting:

The goal of the rehabilitation evaluation is to: 1) assess the patient's needs, 2) define the goals for the rehabilitation, 3) determine the initial prescription for exercise, 4) establish a positive relationship between the participant and the Study Center. The initial evaluation of the HF-ACTION participants will include a 6-minute walk test and a maximal exercise test with breath-by-breath expired gas measurements, as well as quality of life measurements and physical assessment. The training heart rate range will be determined by the Study Center, with oversight from Duke University (Dr. Stuart Russell or his designee). This will be provided to the rehabilitation program at the time of cardiac rehabilitation enrollment. Enrollment in a cardiac rehabilitation program will be within one week of initial testing.

b. Rehabilitation Initiation (Supervised Rehabilitation – weeks 1-6):

The supervised exercise component includes 36 exercise sessions, consisting of sessions three times a week for twelve weeks. Rehabilitation should be initiated within one week after the initial testing. When rehabilitation is provided at a satellite rehabilitation center, the regional Study Center staff must monitor the progress of patients weekly.

- c. **Rehabilitation Completion (Supervised Rehabilitation – weeks 7-12):**
During the second half of the supervised exercise training, participants will be asked to exercise two days a week at home in addition to the three day/week supervised training. The participants will be given additional information on this aspect of their training program at the appropriate time.
- d. **Home Exercise Program:**
After completion of the 36-session supervised rehabilitation, participants will be asked to exercise at home six days a week, and they will again be given instructions for this prior to their discharge from the cardiac rehabilitation program. Participants will return to the cardiac rehabilitation program for monthly sessions during the first six months of the program (months 3-9 of the HF-ACTION study), and then every three months for the duration of the HF-ACTION study.

1.4 Supervised Rehabilitation

The purpose of the supervised rehabilitation program is to provide the following to the participant and family or significant other:

- a. A prescription of exercise therapy (cardiac rehabilitation)
- b. Education on the specific exercises that comprise a cardiac rehabilitation program
- c. Educational material for the patient with heart failure
- d. Development of a relationship between the participant and the Study Center

2. Exercise Training

2.1 Exercise Prescription

- a. **Mode:** Aerobic exercise via either treadmill or stationary bicycle or both (the participant should be started based upon available exercise equipment at home or his/her preference to improve compliance once discharged to the home program component). Patients should avoid arm ergometers, rowers, and water activity. Dual action bicycles, free walking on a path or track is appropriate as long as the patient achieves the target heart rate/RPE goals. Patients may be initiated on recumbent bicycle for the first two weeks with the goal to progress to upright cycling by week three of the program.
- b. **Initial aerobic intensity:** Starting point is greater than or equal to 60% of heart rate reserve (HRR).

$$\text{HRR} = \text{Peak exercise HR} - \text{Resting HR}$$
 Resting heart rate is obtained after five minutes of rest in a quiet sitting position.

$$\text{Initial Training HR} = [(0.6 \times \text{HRR}) + \text{Resting HR}]$$
- c. **Upper heart rate training intensity:** Upper heart rate will not be allowed to exceed the heart rate corresponding to four beats below the ventilatory threshold (VT) as determined by the exercise test. If VT could not be determined, then patients will not be permitted to exceed 65% of HR reserve, with the use of a Borg Rating of Perceived Exertion (RPE) ranging from 12 and 14 (see Appendix A). Participants with ischemia will have a maximum HR 10 bpm below the onset of ischemic EKG changes on exercise testing. Appropriate training HR ranges will be provided by the Study Center (with oversight from Dr. Russell or designee, Duke University).
- d. **Initial conditioning:** This will occur during weeks 1-2, and will consist of a 10 minute warm up, 15-30 minute program, and a 10 minute cool down with a total time 35 to 50 minutes.
- e. **Improvement phase:** Weeks 3-12 will be the improvement phase of the training program. The aerobic portion of this phase will be 30-35 minutes, with a 10 minute warm up and 10 minute cool down for a total time of 50-70 minutes. After 12 weeks of supervised training, patients will exercise at home in the maintenance phase. Appropriate instructions for home exercise will be provided. The training schedule is outlined on the next page:

Training Phase	Location	Weeks into Study	Sessions per week	Aerobic minutes	Intensity (% HRR)	Training Mode
Initial conditioning	Cardiac Rehab	1-2	3	15-30	60%	Walk/Cycle
Improvement	Cardiac Rehab	3-12	3	30-35	70%	Walk/Cycle
Maintenance	Home	12-end	6	40	60-70%	Walk/Cycle

- f. **Frequency of supervised exercise:** Beginning in week 7, participants will be asked to exercise independently 2 times a week in addition to the standard supervised training. They will be given instructions for this phase of their training program by the Study Center. After the completion of the 36 sessions of training, participants will return on a periodic basis for supervised training as outlined in the table below:

	Supervised	Home
Week 1-6	3 sessions/wk	0
Week 7-12	3 sessions/wk	2 sessions/wk
Week 13-36	1 session/month	6 sessions/wk
Week 37-end	1 session/3 months	6 sessions/wk

Please see Appendix B for a more detailed listing of training intensity and duration.

- g. **Warm up and cool down:** A warm up period will be performed ten minutes immediately prior to the exercise program at an intensity of 50% of the training intensity. The cool down will be performed for 10 minutes immediately following exercise at an intensity of 50% of the training intensity.
- h. **Progression of the exercise training during rehabilitation:**
- i. Exercise session duration, intensity, and progression are symptom-limited
 - ii. Increase session duration to the goal of 30-35 minutes of continuous exercise
 - iii. Once the session duration reaches 30-35 minutes, increase the exercise intensity by increasing the watts if using a stationary bicycle, or the speed/incline if using a treadmill
 - iv. Increase intensity gradually to build tolerance and confidence, with the goal of reaching a maximum tolerated workload during each period of exercise
 - v. If the participant cannot perform continuous exercise for the designated duration, interval training should be used with rest periods not exceeding 5 minutes and a goal of 50% HRR and 15-30 minutes of total exercise time. However, the participant should also work toward the goal of 30-35 minute continuous exercise at 60-70% HRR by the end of the 36 session program.
- i. **Maintenance visits:** Maintenance visits will be required monthly for the first 6 months after completion of the 36 exercise session, and every 3 months thereafter until the completion of the HF-ACTION program. During these visits, participants should again perform 30-35 minutes of aerobic exercise with a target HR of 70% of HRR, unless the Study Center provided a new target training HR. 10 minutes of warm-up and cool down at 50% of the training exercise intensity should be provided. If the participants have not been exercising at home, or if they had recent heart failure exacerbation, they may not be able to exercise at the intensity at the end of the 36 session supervised training. In that case, exercise intensity should be adjusted to achieve target HR without untoward symptoms (please see 2.3 Patient Safety).

- j. **Equipments and exercises permitted:** Please note that treadmill and bicycle are the **ONLY** pieces of equipment allowed for use in the HF-ACTION program. This means that stair-steppers, recumbent bicycles (except during initial two weeks of program), free or machine weights, wall pulleys, or resistive bands are **NOT** allowed as part of this program, either during the supervised or home-based phases of this program.
- k. **Education:** The exercise sessions should include instruction about the nature of the exercise, patient safety during the exercise, and self monitoring including pulse assessment, use of the Borg RPE scale and proper use of the heart rate monitors. Please see **Appendix C** for the educational topics that should be covered during the 12 weeks of supervised rehabilitation.
- l. **Timing of medications:** All participants should be instructed to take their cardiac medications between 2 and 10 hours before the beginning of exercise. This includes beta-blockers, which could affect the training HR response.

2.2 Patient Monitoring

While telemetric monitoring is commonly utilized in cardiac rehabilitation programs, this is not required by the HF-ACTION study. Telemetry may be utilized if available in your program. The goal of HF-ACTION is to provide the participants with an independent assessment of the exercise intensity, both through the use of the RPE scale (12-16), as well as the use of heart rate monitors (60-70% HRR).

The following vital signs should be obtained and recorded for each rehabilitation session:

- a. Weight before starting exercise
- b. Resting pulse, blood pressure, RPE
- c. Pulse, blood pressure, RPE during each type of exercise (treadmill, bicycle)
- d. Pulse, blood pressure, RPE after completion of cool-down

All participants in supervised rehabilitation in the HF-ACTION study will be provided with a heart rate monitor. Please see **Appendix D** for the operational aspects of the Polar A1 or S610 monitors. The following goals will enhance the successful utilization of these heart rate monitors:

- a. Participant will be taught how to connect and start and stop HR monitoring device during sessions 1-5.
- b. Participant will be taught how to collect total exercise time and mean HR during exercise during sessions 1-5.
- c. Participant will be proficient with a) and b) by the 6th rehabilitation session.
- d. Participant will be taught about the typical device operational problems and how to troubleshoot (**see Appendix D for handout to patient**).
- e. Participant will be given contact number for the Core HR Monitoring Lab for technical assistance (Mr. Clinton Brawner, phone #: _____).
- f. Participant will learn to use device to record HR during each phase of exercise using wristwatch.
- g. Participant will learn how to count pulse by palpation if the HR monitoring device is not working or available. **It is important to stress that a nonfunctional device is not a reason to miss an exercise session.**
- h. During weeks 7-12 of supervised rehabilitation, participants will begin home exercise 2 days a week – they are expected to fill out a home exercise log (**Appendix E**), including exercise duration, symptoms and heart rate. Participants are expected to bring this exercise log to the cardiac rehabilitation program once a week for review with the rehabilitation staff.
- i. Participants must demonstrate proficiency with these tasks before discharge from the supervised rehabilitation program at the end of week 12.

2.3 Patient Safety

Even though previous studies have demonstrated the safety and efficacy of exercise training in patients with NYHA class II-IV heart failure, the applicability of this to a larger, unselected population of heart failure patients is unknown. Since this is a research study, participant safety is of utmost importance. Since telemetry will not be available at all HF-ACTION training sites, the following are simplified guidelines that apply to all programs. The exercise session should be interrupted if a participant develops one or more of the following:

- a. Symptomatic hypotension or decrease in blood pressure > 10 mmHg from resting blood pressure
- b. Hypertension (systolic blood pressure > 250 mmHg or diastolic blood pressure > 115 mmHg)
- c. Moderate to severe angina
- d. Severe dyspnea
- e. Severe palpitations, with associated lightheadedness
- f. Defibrillator discharge
- g. Claudication
- h. Disabling knee/ankle pain

2.4 When to Contact Study Center

The Study Center should be contacted for any of the following problems:

- a. Participant did not show up for a session
- b. Exercise session interrupted for any reason
- c. Participant not able/willing to keep up with training goals
- d. Significant weight gain of ≥ 5 pounds between exercise sessions
- e. Any adverse event which necessitated an emergency room visit or hospitalization
- f. Any questions about the protocol procedures or training intensity

The contact numbers for the Study Center staff are as follows:

- | | | | |
|----|----------------------------------|-----------------|-------|
| a. | Coordinator _____ | Phone #: _____ | _____ |
| | | Beeper #: _____ | _____ |
| | | Fax #: _____ | _____ |
| b. | Principal Investigator _____ | Phone #: _____ | _____ |
| | | Beeper #: _____ | _____ |
| | | Fax #: _____ | _____ |
| c. | Other Study Center Contact _____ | Phone #: _____ | _____ |
| | | Beeper #: _____ | _____ |
| | | Fax #: _____ | _____ |

In addition, the case report forms for each session should be faxed to the Study Center weekly. **Correctly completed forms will be the only mechanism through which payment can be generated to your center.**

2.5 Discharge Checklist

Appendix F includes a discharge checklist to be completed at the end of the 12-week cardiac rehabilitation program. It is important to ascertain which exercise equipment the participant will be working on primarily (treadmill or bicycle), and whether they have this equipment at home. If not, the HF-ACTION program will loan either a treadmill or bicycle (participant preference) to them for use for the duration of the study. In addition, it is important to make sure at the conclusion of the 36 sessions that all paperwork for this study has been faxed to the Study Center. Once again, receipt of properly completed forms is the only mechanism through which payment can be generated to your program. Finally, it is important to make sure all educational topics have been covered during the 12-week program. The original checklist should be kept for your program files, and a copy should be faxed to the Study Center.

Appendix A. Rating of Perceived Exertion Scale

Rating of perceived exertion (RPE) is another tool used to monitor an individual's exercise tolerance. The scale correlates with exercise heart rates and work rates (REF). The scale is used to rate how hard the patient feels he or she is working, and will account for fatigue, environmental conditions, and fitness levels. Although two scales are available, HF-ACTION will utilize the 6 to 20 scale, as this is what outpatient cardiac rehabilitation programs most often utilize. It has been determined that the level of "12" to "16", with the word choices of "somewhat hard" or "hard", corresponds to the threshold for blood lactate accumulation.

It is important to use the standardized instructions for patients to reliably use the RPE scale. The recommended instructions are follows:

"During the exercise we want you to pay close attention to how hard you feel the exercise work rate is. This feeling should reflect your total amount of exertion and fatigue, combining all sensations and feelings of physical stress, effort, and fatigue. Don't concern yourself with any one factor such as leg pain, shortness of breath or exercise intensity, but try to concentrate on your total, inner feelings of exertion. Try not to underestimate or overestimate your feelings of exertion; be as accurate as you can."

Patients should remain between 12 and 14 during exercise sessions.

Borg RPE Scale

6	
7	Very, very light
8	
9	Very light
10	
11	Fairly light
12	
13	Somewhat hard
14	
15	Hard
16	
17	Very hard
18	
19	Very, very hard
20	

Borg GAV. Psychophysical bases of perceived exertion. Med Sci Sports Exer 1982;14:377-381.

Appendix B
Overview of Exercise Progression

Program Stage	Week	Dates	Supervised Exercise Frequency (Sessions per week)	Exercise Intensity	Exercise Duration (Minutes)	Home Exercise Program (Sessions per week)	Comments
Initiation	1	/ to /	3	60%	15-30		
	2	/ to /	3	60%	15-30		
Improvement	3	/ to /	3	70%	30-35		
	4	/ to /	3	70%	30-35		
	5	/ to /	3	70%	30-35		
	6	/ to /	3	70%	30-35		
	7	/ to /	3	70%	30-35	2	
	8	/ to /	3	70%	30-35	2	
	9	/ to /	3	70%	30-35	2	
	10	/ to /	3	70%	30-35	2	
	11	/ to /	3	70%	30-35	2	
	12	/ to /	3	70%	30-35	2	
Maintenance (Home program)	13-16	/ /	1/month	70%	40	6	
	17-20	/ /	1/month	70%	40	6	
	21-24	/ /	1/month	70%	40	6	
	25-28	/ /	1/month	70%	40	6	
	29-32	/ /	1/month	70%	40	6	
	33-36	/ /	1/month	70%	40	6	
	37-48	/ /	1/3 months	70%	40	6	

Appendix C

Patient Education Topics *(check and date once completed)*

- 1. General Benefits of Exercise ()
 - Cardiovascular
 - Improves functional capacity
 - Lowers resting/exercise heart rate
 - Lowers blood pressure
 - Improves lipids
 - Improves body fat/muscle composition
 - Musculoskeletal
 - Increases muscle strength/endurance
 - Improves flexibility
 - Prevents injury
 - Increases bone mass
 - Increases coordination/balance
 - Improves insulin sensitivity
- 2. What to Expect With Single-Bout Exercise ()
 - Initial rapid rise of heart rate with exercise when starting program
 - Improvement of exercise heart rate response with conditioning
 - Need for increasing workload to maintain training heart rate
 - Importance of maintaining training HR for prescribed duration
 - Role of interval training
- 3. Safety of Exercise ()
 - Role of warmup/stretching
 - Role of cooldown
- 4. Proper Intensity of Exercise ()
 - Purpose of training HR
 - Use of polar HR monitor
 - Use of RPE 12-14 during HF-ACTION study
- 5. Normal Responses to Exercise ()
 - Dyspnea
 - Diaphoresis
 - Leg fatigue/soreness
 - Arthralgias/Joint stiffness
 - Acceptable treatment modalities for muscle/joint soreness (no NSAIDs)
- 6. Abnormal Symptoms With Exercise ()
 - Angina
 - Severe dyspnea (use of Dyspnea Index)
- 7. Safety of Exercise ()
 - Proper attire/shoes
 - Eating before exercise
 - Timing of cardiac medications (2-10 hrs before exercise – be consistent)
 - Outdoor conditions (excessive heat/humidity/cold/pollutants)

Appendix F

Discharge Session Checklist (*check and date once completed*)

- 1. Instructed in expectations for compliance with home exercise regimen ()
- 2. Instructed in pulse rate palpation ()
- 3. Instructed in Borg rate of perceived exertion scale ()
- 4. Instructed in heart-rate monitor ()
- 5. Completed educational topics ()
- 6. Appointment made for next follow up session ()
- 7. Forms faxed to Study Center ()

Patient Equipment (please check what applies)

- Patient has stationary bicycle at home
- Patient has treadmill at home (not a manual treadmill)
- Patient will require a stationary bicycle for use at home
- Patient will require a treadmill for use at home

Name of Rehab Personnel Completing Form

Signature of Rehab Personnel Completing Form