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## **New international study to test exercise in heart failure patients**

WINSTON-SALEM, N.C. -- Cardiologists at Wake Forest University Baptist Medical Center are helping to lead a large international study involving 83 other sites that will test 3,000 patients in an effort to determine whether exercise really is good for heart failure patients.

Though doctors have promoted the value of exercise for a variety of disorders for years, "exercise training has not been definitively established as safe in the group of patients who primarily have heart failure," said Dalane W. Kitzman M.D., a cardiologist who is principal investigator at Wake Forest Baptist, and colleagues, writing in the American Heart Journal.

"Controlled clinical trials have shown that exercise training improves physiological measurements" such as the distance that patients can walk in six minutes, they said after analyzing 14 trials. "None of these trials enrolled a sufficient number of patients to properly evaluate the impact of exercise training on death and hospitalization."

The new trial, called Heart Failure and A Controlled Trial Investigating Outcomes of Exercise Training (HF-ACTION) "is the largest randomized clinical trial of exercise training ever performed," Kitzman said. "The trial represents a critical step in establishing exercise as a therapy for patients with left ventricular dysfunction" (reduced heart contractions).

He added, "The patient population enrolled in this trial will be a broad representation of heart failure patients, including large numbers of women, minorities and people from low socio-economic status."

"The HF-ACTION trial has been designed so that if the intervention is beneficial, the treatment can be translated rapidly into general practice," Kitzman said. In fact, the study leaders have met with Centers for Medicare & Medicaid Services, the office that assesses whether there is enough proof that a treatment is effective and safe in order to be paid for by Medicare, to help ensure that exercise programs would qualify for Medicare if the study is positive.

There are 84 clinical study sites in the trial across North America and Europe. At the Wake Forest Baptist site, 120 participants have been enrolled so far, the second-highest number across all sites.

The patients in the study will receive either exercise training or "usual care." Those in the exercise arm will receive 36 supervised exercise training sessions at a facility, using either bikes or walking. After the first 18 sessions, the patients will start home-based exercise, and will exercise exclusively at home after the second 18 sessions. They'll come back for facility-based training every three months.

The supervised training protocol is based on the traditional cardiac rehabilitation program of 36 sessions currently covered by insurers for patients after heart bypass surgery.

All patients in HF-ACTION will receive a self-management education program on topics such as medicines and their side effects, managing fluids, the importance of adhering to a low sodium diet.

The patients will be followed for up to four years through clinic visits, specialized tests, and telephone calls. In their comparison of the two groups, the investigators will record deaths and hospitalizations for all causes. They'll also measure changes in the maximum exercise time and quality of life.

Vinay Thohan, M.D., director of the heart failure service at Wake Forest Baptist, said "Five million Americans have heart failure with 550,000 new cases diagnosed each year. Despite optimal drug treatment, many heart failure patients die and others are faced with repeated hospitalizations, and have difficulty getting around, even for a few steps.

"Exercise training represents an intervention that if proven beneficial should be accessible to most heart failure patients due to its relatively low cost, high availability and ease of use," Thohan said.

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Wake Forest University Baptist Medical Center is an academic health system comprised of North Carolina Baptist Hospital and Wake Forest University Health Sciences, which operates the university's School of Medicine. The system comprises 1,187 acute care, psychiatric,

rehabilitation and long-term care beds and is consistently ranked as one of "America's Best Hospitals" by U.S. News & World Report.

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