Exercise training in Diastolic Heart Failure (Ex-DHF): rationale and design of a multicentre, prospective, randomized, controlled, parallel group trial.

Heart failure with preserved ejection fraction (HFpEF) is a common disease with high incidence and increasing prevalence. Patients suffer from functional limitation, poor health-related quality of life, and reduced prognosis. A pilot study in a smaller group of HFpEF patients showed that structured, supervised exercise training (ET) improves maximal exercise capacity, diastolic function, and physical quality of life. However, the long-term effects of ET on patient-related outcomes remain unclear in HFpEF. The primary objective of the Exercise training in Diastolic Heart Failure (Ex-DHF) trial is to investigate whether a 12 month supervised ET can improve a clinically meaningful composite outcome score in HFpEF patients. Components of the outcome score are all-cause mortality, hospitalizations, NYHA functional class, global self-rated health, maximal exercise capacity, and diastolic function. After undergoing baseline assessments to determine whether ET can be performed safely, 320 patients at 11 trial sites with stable HFpEF are randomized 1:1 to supervised ET in addition to usual...
care or to usual care alone. Patients randomized to ET perform supervised endurance/resistance ET
(3 times/week at a certified training centre) for 12 months. At baseline and during follow-up,
anthropometry, echocardiography, cardiopulmonary exercise testing, and health-related quality of life
evaluation are performed. Blood samples are collected to examine various biomarkers. Overall
physical activity, training sessions, and adherence are monitored and documented throughout the
study using patient diaries, heart rate monitors, and accelerometers. The Ex-DHF trial is the first
multicentre trial to assess the long-term effects of a supervised ET programme on different outcome
measures in patients with HFpEF.