Family Focused Nursing for outpatients with heart failure – a randomized multicenter trial

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Background
Quality of life is impaired for patients with heart failure and their next of kin, compared to other patients suffering from chronic diseases. Increased focus on relations between patients and health professionals in combination with social support from an active network might contribute to further improvement in health status of the patients. However, studies up to now have primarily used descriptive design with small population showing diverging results and variation in the definition of social support. A well designed randomised trial is needed in order to conclude whether Family Nursing Care can be justified as supplement to current course of after care of patients with heart failure and their close relatives. The purpose is to evaluate the effect of Family Focused Nursing versus conventional treatment of heart failure outpatients with respect to health-related quality of life, illness management (self-care, family resources, self-efficacy and depression) re-admissions and mortality.

Design
The study is designed as a randomized multi-centre trial at three Danish heart failure clinics, consecutively, including 468 patients allocated to one of two groups. Inclusion of patients started in June 2011. Patients are centrally randomized by an external online computer based system. All patients will receive standard treatment by teams specialising in heart failure. The nurse intervention, focus on identifying problems and resources, and to strengthen the family's management of the illness, in the areas of cognitive, affective and behavioural functions.

Description of the cohort
Patients from three heart failure outpatient clinics at Odense University Hospital, Hospital Lillebaelt Vejle and Bispebjerg Hospital are enrolled consecutively after confirmation of the heart failure diagnosis according to the Framingham criteria based on left ventricular ejection fraction \( \leq 40\% \); referral to follow up nursing care in a HF clinic; New York Heart Association classification II-IV symptoms and signed informed consent. Patients who don't understand and speak Danish; who are in terminal stage of other serious diseases with a life expectancy less than six months and not able to give informed consent will excluded from the study.

Current status
Enrollment of patients ended in January 2016 and the first data regarding 3 months follow-up, will be analyzed and the results reported during spring 2016.