Hybrid telerehabilitation in heart failure patients (TELEREH-HF) a randomized, prospective, open-label, parallel group, controlled, multi-center trial - study design and description of the intervention

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Background Current guidelines strongly recommend exercise training as an important component of heart failure (HF) management. Despite this, there are large regional disparities in access to rehabilitation both in Poland and in Europe. One of the possibilities to solve this problem is to introduce hybrid telerehabilitation (TR) in HF patients (pts). Purpose The primary objective of the TELEREH-HF trial is to determine whether introducing a novel hybrid model of TR in HF will significantly increase days alive and out of hospital when compared with usual care. The secondary objectives are to assess the effects of a hybrid TR compared to usual care on all-cause and cardiovascular mortality and all-cause, cardiovascular and heart failure hospitalization. The tertiary analyses will include: evaluation of the safety, effectiveness, quality of life (QoL), depression, anxiety, pts acceptance of and adherence to a hybrid TR. Methods The TELEREH-HF study is designed as a randomized (1:1), prospective, open-label, parallel group, controlled, multi-center (5 centers) trial among 850 clinically stable HF pts after a hospitalization incident, NYHA I-III, LVEF=40%. Eligible pts were randomized to either hybrid TR+usual care (telerehabilitation group[TG]) or to usual care only (control group[CG]) and are followed for a maximum of 24 months. The TG pts underwent a 9-week hybrid TR program consisting of an initial stage (1 week) conducted at hospital and a basic stage (8-week) home-based TR five times weekly. The goals of the initial stage are: a baseline clinical examination, education, individual planning of exercise training and performing a few monitored educational training sessions. The TG pts received a device for remote supervision of the exercise training (telemonitoring ECG, blood pressure, weight). The primary study outcome is the number of days alive and out of hospital (DAOH) in the 12 months following the end of the preliminary 9-week training program. Secondary outcomes assessed at 12 months include all-cause and cardiovascular mortality, all-cause, cardiovascular and heart failure hospitalization. Secondary outcomes assessed at 9 weeks include: the effectiveness based on peak oxygen consumption in cardiopulmonary exercise test and the distance in 6-minute walking test; the QoL based on SF-36 Survey; the depression based on Beck inventory; the anxiety based on STAY; the acceptance based on questionnaire and the adherence based on the percentage of pts who carried out the prescribed exercise training. Results All pts were randomised and completed the intervention (TG) and observation (CG) period. The follow up is now in progress. The results will be available in 2019/2020. Conclusion The TELEREH-HF trial will provide novel data on the effect of the hybrid TR on days alive and out of hospital, hospitalization and mortality in HF pts and safety, effectiveness, QoL, depression, anxiety and pts acceptance of and adherence to this intervention.