Rationale of a study for patient empowerment and shared decision support for cardiorenal syndrome

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Introduction

Early detection and aggressive management of underlying causes and comorbidities are the most important aspects of cardiorenal syndrome. Preventing progression to end stage renal and/or cardiac deficiency may improve quality of life and help save health care costs. CARRE (Personalized patient empowerment and shared decision support for cardiorenal disease and comorbidities, EU-FP7 funded project, no.611140) employs internet aware sensors and sources of medical evidence to compile a variety of personalized alerting, planning and educational services. Within this project, patients are empowered and can make shared informed decisions.

Objectives

Primary objectives are: to increase health literacy; to increase level of patient empowerment; to improve patient quality of life; to reduce the personal risk of cardiorenal disease related morbidities (as these are described in the CARRE risk factor database). Secondary objectives are: to ameliorate or prevent the progression of clinical and laboratory parameters related to cardiorenal disease and comorbidities; improve lifestyle habits (smoking, physical activity, adherence to self-monitoring and therapy); limit the number or dose of essential drugs; test for intervention acceptability and/or user satisfaction.

Methods

Pilot study is ongoing at two sites, Vilnius University (Lithuania) and Democritus University of Thrace (Greece). Study population (total 160 patients) enrolls two groups of individuals: group 1 (40 patients) consists of patients with a diagnosis of metabolic syndrome according to criteria based on the Joint Interim Statement; group 2 (40 patients) consists of patients with either renal or heart disease, diagnosed as chronic kidney disease (CKD) stage 3a or CKD stage 2 with albuminuria or systolic heart failure, NYHA class II or III. Group 1 and group 2 are divided further into intervention and control groups (20 patients each). The patients in intervention group are trained to work with CARRE user interface, and scheduled to monitor their parameters with telemedicine devices at home: blood pressure monitor, scale, physical activity tracker, glucometers. The patients in control group have traditional medical care. The study started in July 2016.

Study population, 80 patients, 2 pilot sites

Patients at risk of heart or renal disease (n=40)

Patients with heart or renal disease (n=40)

Randomisation in each group

Control group
1. Standard patients care
2. Checking health records
3. Providing information about health related status
4. Giving recommendations how to collect and monitor health data conventionally

CARRE group
1. Standard patients care
2. Checking health records
3. Signing patients to CARRE service
4. Giving and demonstrating personal sensors
5. Giving instructions how to collect measurements, plan and monitor health status with CARRE

Results

The study team in Nephrology center (Vilnius University Hospital Santariskiu Klinikos) enrolled 20 patients with CKD (median age 50.6), 10 patients in group 1 and 10 patients in group 2 (5 male and 5 female in each group). The intervention group (mean age 43.3) consists of 4 patients with CKD stage 2 with albuminuria, and 6 patients with CKD stage 3. Most patients (5) have a diagnosis of glomerulopathy. The control group (mean age 57.9) consists of 3 patients with CKD stage 2 with albuminuria, and 7 patients with CKD stage 3. Most patients (4) have a tandem diagnosis of diabetes and hypertension. All patients had screening and baseline visits, were register in CARRE platform, and underwent measurements and collection of required medical records.

Conclusion

The ultimate goal is to help patients with comorbidities take an active role in care processes, including self-care and shared decision making, and also to support medical professionals in understanding and treating comorbidities via an integrative approach. The first project results on the analysis of the cardiorenal disease and related sources of medical evidence are expected in the end of 2016.

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