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**A PROTOCOL FOR A RANDOMIZED CLINICAL TRIAL OF  
A NOVEL EMPOWERMENT SYSTEM FOR CARDIORENAL  
PATIENTS**

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**Objectives:** Early detection and aggressive management of underlying causes in cardiorenal disease and comorbidities requires patient awareness, education and self-management. This study presents a protocol for evaluating the efficacy of a novel web-based service for the personalized prevention, empowerment and shared decision support in cardiorenal disease and comorbidities (outcome of CARRE EU-FP7 funded project, no. 611140).

**Methods:** CARRE service presents patients with an interactive graph that shows personalized risks based on personal health status as derived from personal medical data and mobile sensors. The service supports planning lifestyle changes to lower risks and improve odds for disease progression, and offers intuitive alerts to help patients to adhere to efficient self-monitoring and lifestyle management. The design of this clinical trial allows evaluation of CARRE service efficacy to increase health literacy and patient empowerment patients, and to improve quality of life and medical condition.

**Results:** This randomized controlled study addresses two different intervention populations, patients at risk (mainly metabolic syndrome) and patients with either heart or renal disease. The intervention arm includes use of CARRE service in addition to standard care while the control arm includes standard care. Primary outcomes include increase in health literacy, perceived quality of life and level of empowerment and reduction of personal risk.

**Conclusion:** This clinical trial will evaluate a web-based patient empowerment and self-management service for cardiorenal disease and comorbidities.