

A Protocol for a Randomized Clinical Trial of a Novel Empowerment System for Cardiorenal Patients

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Introduction

Early detection and aggressive management of underlying causes in cardiorenal disease and comorbidities requires patient awareness, education and self-management. The CARRE project funded by European Commission employs internet aware sensors and sources of medical evidence to compile a variety of personalized alerting, planning and educational services so that patients are empowered and can make shared informed decisions.

Objectives

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. This study aims to design a clinical investigation protocol to evaluate the efficacy of the CARRE web-based service.

Methods

The design of this clinical trial protocol took into account evaluation along four different axes:

- the efficacy of CARRE service to increase health literacy (HLS-EU-Q questionnaire)
- the ability of CARRE service to empower patients (SUSTAINS questionnaire)
- the impact of CARRE service to improve quality of life (SF-36 questionnaire)
- improve the medical condition of the patient

Study Primary Objectives

1. Increase health literacy
2. Increase level of patient empowerment
3. Improve patient quality of life
4. Reduce the personal risk of cardiorenal disease related morbidities

Study Secondary Objectives

1. Ameliorate the progression of clinical and laboratory parameters
2. Improve lifestyle habits
3. Limit essential drugs
4. Assess user satisfaction

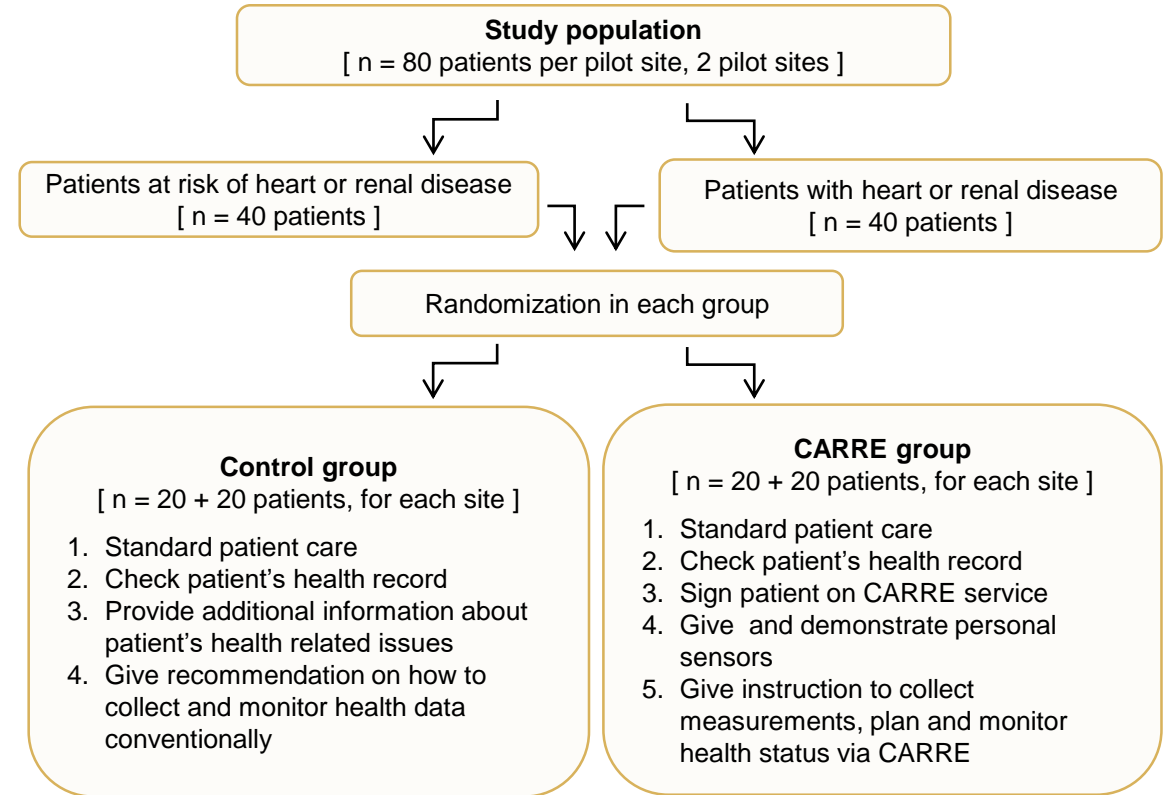
Acknowledgments



This work was supported by the FP7-ICT project CARRE (No. 611140) co-funded by the European Commission. <http://www.carre-proect.eu/>



Results



Conclusions

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

References

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