



CARDIOCARE

**An Interdisciplinary Approach for the Management of
the Elderly Multimorbid Patient with Breast Cancer**



CARDIOCARE has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 945175.

THE CARDIOCARE PROJECT

Introduction

Evidence-based best practices for risk stratification of elderly breast cancer patients are still lacking. Data for this patient population are scarce, since elderly patients are underrepresented in clinical oncology trials. Consequently, lower doses of chemotherapy are prescribed due to concerns for the onset of cardiotoxicity, frailty bias and high prevalence of multimorbidity¹. This contributes to the undertreatment of patients with a negative impact on their Quality of Life (QoL)². The CARDIOCARE project, which began on July 2021, addresses this challenge and has been developing a novel risk stratification and healthcare model, based on new sets of quality key performance indicators, digital and imaging biomarkers, providing evidence-based best practices and care pathways to improve the management of multimorbid breast cancer patients at risk for cardiotoxicity.

CARDIOCARE has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 945175 and is a collaborative effort from 12 partners, leading scientists in 7 countries across Europe (Greece, Italy, Cyprus, Slovenia, Sweden, Netherlands, and France).

“Cardiovascular disease is a devastating complication of anti-cancer treatment that affects physical and mental health”

Prof. Dimitrios Fotiadis, Coordinator

The goal of the project is to gather experts from different scientific fields across Europe including clinical oncologists, cardiologists, psychologists, molecular biologists, bioinformaticians and biomedical engineers in order to improve the monitoring, treatment and overall care provided to the breast cancer patient above 65 years of age. Through an

¹ Baris et al. Management of Cardiovascular Disease in Women With Breast Cancer, *Circulation*. 2019;139:1110-1120

² Reddy P et al. Cardio-oncology in the older adult. *J Geriatr Oncol*. 2017;8(4):308-314

individualized care plan the project aims to provide patients with the ability to take part in their care process and improve their physical condition and psychological adaptation to the disease.



Figure 1: The CARDIOCARE consortium

CARDIOCARE innovation relies upon the integration of:

- retrospective and prospective clinical data
- patient-oriented eHealth mobile application
- wearable sensors
- advanced data mining and machine learning approaches for the creation of risk stratification models of cardiotoxicity.

Retrospective and Prospective Clinical Study

CARDIOCARE exploits existing retrospective real-world data of 1.587 elderly breast cancer patients from the 5 clinical centers³. The aim of the study is to define the Key Performance Indicators (KPIs) for effectively monitoring cardiotoxicity, health status, intrinsic capacity and

³ The 5 clinical centers for the **retrospective study**: European Institute of Oncology (IEO) - Italy, Bank of Cyprus Oncology Centre (BOCOC) - Cyprus, Karolinska University Hospital (KSBC) - Sweden, National and Kapodistrian University of Athens (NKUA) - Greece and University of Ioannina (UOI) - Greece.

QoL during the disease continuum. The retrospective data include cardiac imaging data, breast imaging, biomarker and psycho-markers data, blood examination data and QoL data.

In parallel, a prospective clinical study is in progress (recruitment started in April 2023). Multidimensional data including clinical, genomic, biochemical, behavioural and imaging (echocardiography, mammography) from 750 elderly breast cancer patients from the 6 clinical sites⁴ will be collected. The data are gathered in the hospital (during clinical visits) and in ecological context, through the CARDIOCARE mobile application and digital biomarkers from sensor devices (physical activity sensor, ECG sensor). The data will be explored by machine learning approaches, to uncover novel factors and pathways linked to cardiotoxicity onset, impairment of patients' intrinsic capacity and QoL.

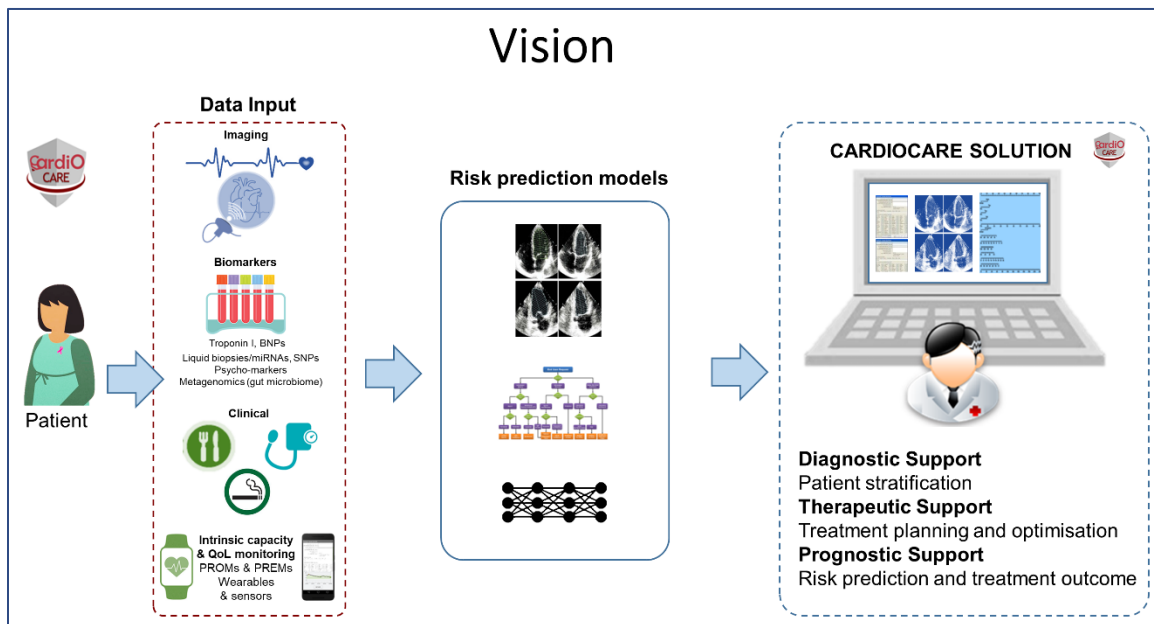


Figure 2: The CARDIOCARE Vision

The CARDIOCARE application

Currently, no extensive studies have allowed the collection of all necessary data to make a meaningful assessment of elderly breast cancer patients' intrinsic capacity and QoL. The CARDIOCARE mobile application has been designed to support the user-friendly collection of data and the monitoring of patients' intrinsic capacity and QoL. By using the innovative eHealth approach of the CARDIOCARE mobile application and technologically advanced wearable

⁴ The 6 clinical centers for the **prospective study**: European Institute of Oncology (IEO) - Italy, Bank of Cyprus Oncology Centre (BOCOC) - Cyprus, Karolinska University Hospital (KSBC) - Sweden, Institute of Oncology Ljubljana (IOL) - Slovenia, National and Kapodistrian University of Athens (NKUA) - Greece and University of Ioannina (UIO) - Greece.

devices, the CARDIOCARE prospective study pursues a twofold aim: (a) testing the effectiveness of the CARDIOCARE mobile application to monitor, assess, and improve elderly breast cancer patients' intrinsic capacity and QoL; (b) developing a holistic, patient-centered risk prediction model able to detect cardiotoxicity before it clinically emerges.

Patients assigned to control and supportive care arms have access only to the ePsychHeart application. The ePsychHeart application monitors patients' QoL, caregiver burden, and intrinsic capacity including:

- psychological and cognitive states
- mobility and locomotion
- vitality status
- sleep overview/fatigue, grip strength

Complementary to the ePsychHeart monitoring, behavioral and psychological interventions to preserve intrinsic capacity and QoL and to counteract cardiotoxicity are delivered to the supportive care arm via the eHealthHeart mobile application. The eHealthHeart interventions include psychological interventions, cognitive stimulation, physical activity and performance exercises, together with providing education and support to caregivers. The eHealthHeart interventions are in line with the 2019 American Heart Association Scientific Statement on Cardio-Oncology Rehabilitation⁵, endorsed by the American Cancer Society and with the WHO's guidelines on Integrated Care for Older People (ICOPE)⁶ with evidence-based recommendations for health care professionals to prevent, slow or reverse declines in intrinsic capacity of older people.

⁵ Gilchrist SC et al. Cardio-Oncology Rehabilitation to Manage Cardiovascular Outcomes in Cancer Patients and Survivors: A Scientific Statement From the American Heart Association. *Circulation* 2019; 139(21):e997-e1012.

⁶ <https://www.who.int/publications/i/item/9789241550109>

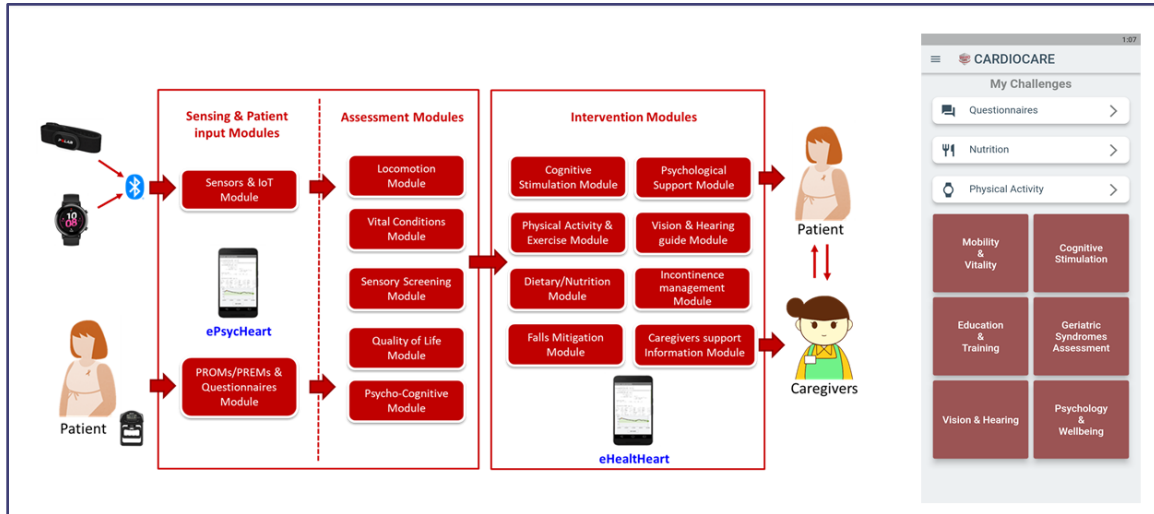


Figure 3: The CARDIOCARE application

Integrated risk stratification model of cardiotoxicity

The image-based risk stratification model exploits echocardiography images to identify new quantitative imaging biomarkers and signatures predictive of cardiotoxicity and patient response. The non-image risk stratification model exploits data from Electronic Health Records, lab tests, circulating biomarkers and the mobile application. The integrated CARDIOCARE risk stratification model combines imaging with non-imaging AI models to enhance decision support for the early diagnosis and management of cardiotoxicity and declines in QoL.

Looking Ahead

The main joint outcomes generated in CARDIOCARE are:

1. Models and algorithms for personalised patient monitoring (risk stratification) and therapy selection incorporating novel biomarkers, psycho-markers for optimal healthcare pathways identification;
2. Novel integrated eHealth behavioral and psychological interventions for improving the intrinsic capacity and QoL and counteract cardiotoxicity in elderly breast cancer patients;
3. A scalable big data management and analysis platform of multidimensional health data, sensor signals, and data from the mobile health application aiming to provide actionable insights and assist clinicians to identify best practices to improve QoL, identify patient care gaps, improve patient outreach by automatically tracking and managing a patient's progress, participation, compliance, preference and satisfaction and support patient-centred care.

4. New validated sets of quality Key Performance Indicators (KPIs), including biomarkers, for patient stratification/monitoring;
5. Structured datasets, including retrospective and prospective clinical and imaging data as well as patient reported outcomes related to emotional and psychological aspects.

For each of the outcomes above different development approaches are possible. For some, CARDIOCARE Consortium is considering an open science approach, while others are considered marketable and the discussion about the different products classification and related development pathways is emerging.

CARDIOCARE Consortium aims to collect comprehensive inputs on the regulatory implications of the different exploitation options, to further guide strategic decisions about the development of the joint outcomes generated.

“CARDIOCARE is on track to improve the physical and mental health of older women with breast cancer by detecting the cardiovascular side effects of anti-cancer treatment early and providing digital tools to help patients improve their mental and physical wellbeing.”

Prof. Dimitrios Fotiadis, Coordinator

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