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EXPLORING ELDERLY MULTIMORBID HEART FAILURE PATIENTS' HEALTH-RELATED QUALITY OF LIFE WITHIN A BLENDED COLLABORATIVE CARE FRAMEWORK: UNDERSTANDING THE ROLE OF CARE MANAGERS

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ABSTRACT

Introduction: Health-Related Quality of Life (HRQoL) is frequently considered a primary efficacy outcome in person-centered treatments for elderly patients with multimorbidity and chronic diseases, such as heart failure (HF). Nonetheless, a deeper understanding of factors related to HRQoL and how they can be addressed by support figures such as care manager (CM), within personalized models, is needed.

Aims: The project is divided into 2 studies which aimed to: 1) explore sociodemographic, clinical, psychological and psychosocial characteristics (i.e. medical adherence, physical and cognitive status, illness perception, health literacy, loneliness, depression, anxiety, stress, treatment burden) on perceived health status, HRQoL (including both global and disease-specific quality of life) among elderly HF patients with multimorbidity (Study 1); 2) explore the perspectives of CMs on their role and functions within a Blended Collaborative Care (BCC) approach (Study 2).

Methods: For Study 1, data from HF patients aged 65 or above with at least 2 medical comorbidities and elevated psychological distress, randomized for the ESCAPE BCC trial in Italy (Horizon 2020, Grant 945377), were used for the analyses. Sociodemographic and medical information was collected based on patients interviews and medical records. HRQoL was assessed through EuroQoL 5 Dimension 5 Level (EQ-5D-5L) to address global quality of life and through the Kansas City Cardiomyopathy Questionnaire (KCCQ-12) for disease specific quality of life. Psychological and psychosocial characteristics were assessed through standardized self-rating instruments. For Study 2, qualitative data from CMs were collected through semi-structured interviews in Italy (N=4) and Denmark (N=2). Data analysis involved open-coding, resulting in themes.

Results: In Study 1, data collected from 33 HF patients (mean age 77.6 ± 6.80 years; males 52%) were analyzed. No significant results related to sociodemographic factors and HRQoL were found. Among clinical factors, NYHA class was negatively associated with better disease-specific QoL in the sample. High perceived health status was associated with a ≤5 years of cardiac disease duration, where number of co-existing disorders and pacemaker had a significant impact on health status. Patients also reported significant differences in disease-specific QoL associated with the use of communication tools (e.g., phone and internet) and anxiety levels, where the latter had a significant impact on global QoL as well. The overall perceived health status, global and disease-specific QoL were significantly associated with patients' physical capability. Additionally, perceived health status of the sample differed based on frailty, illness perception, and depression, where frailty and depression had a significant impact on all QoL types (global, disease-specific and overall health status). Global QoL differed according to physical function and cognitive impairment in the sample, and psychological distress was associated only with disease-specific QoL.

The study 2 revealed that CMs perceive their role as unique in caring for elderly HF patients, emphasizing the importance of trustful relationships and the impact of BCC elements in proactively assisting patients. However, there is still a need to adapt BCC and the CM role into real clinical practice within the local health systems, including the integration of care management tools specifically designed for the research project.

Conclusions: The findings of the present research provided a better understanding of HRQoL determinants in older multimorbid HF patients for further BCC improvement. In addition to clinical characteristics such as NYHA class, years of cardiac disease duration, number of co-existing disorders, and cardiac treatment interventions (e.g., pacemaker), it is crucial for care management to recognize the associations between HRQoL and various factors including communication tools, physical and cognitive status, frailty, illness perception, and psychological distress, such as depression and anxiety, among elderly HF patients with multimorbidity. Lastly, despite CMs perceiving their role as beneficial to patients' HRQoL

improvement, BCC interventions are suggested to be adapted to clinical practice and local healthcare settings.

1. HEALTH-RELATED QUALITY OF LIFE OF ELDERLY MULTIMORBID HEART FAILURE PATIENTS

1.1. Heart failure and multimorbidity among elderly in Italy

The overall estimated prevalence of HF in Italy ranges between 1–2% among the general population, and steadily increases with age (Di Lonardo et al., 2017), where the majority of HF patients, from 40 to 70%, are older adults above 65 years old (Chiu & Cheng, 2007). This age group also showed a high morbidity and mortality rates, emphasizing the severe impact of HF in the elderly (Canepa et al., 2022). In Friuli Venezia Giulia and Lazio Region, HF with "preserved" ejection fraction (EF; HFpEF) was the most prevalent with a mean age of 80 years (Mureddu et al., 2012; Russo et al., 2024). As the population ages in Italy the prevalence and numbers of chronic diseases rises, the number of patients with HF grows, placing additional demands on healthcare resources (Boccardi et al., 2024). Indeed, HF is a leading cause of hospitalization among the elderly in Italy, that increases healthcare demand and strains the National Health Fund (Longo et al., 2024; Maggioni et al., 2023).

Multimorbidity is especially common among elderly HF patients, with over 85% having two or more chronic conditions such hypertension, coronary artery disease, atrial fibrillation, diabetes, dyslipidemia, anemia, chronic kidney disease, chronic obstructive pulmonary disease (COPD), sleep apnea and cancer (Simou et al., 2022). Moreover women tend to present with HF later in life and often have more comorbidities, chronic conditions, compared to men, although they generally have a more favorable survival rate (Heidenreich et al., 2022). In Italy, prevalence of multimorbidity among elderly patients with HF also is notably high. For instance, the IN-CHF registry highlighted that renal impairment and chronic obstructive pulmonary disease (COPD) are common comorbidities in elderly HF patients, with renal dysfunction being a significant independent risk factor for morbidity and mortality (Pulignano et al., 2002). Furthermore, according to Lenzi and colleagues (2016) in Emilia-Romagna 39.9% of patients aged 65 years and older had multimorbidity, with a significant association with age and a higher frequency among Italian citizens compared to immigrants, after adjusting for gender and age (Lenzi et al., 2016). Moreover, there is a geographic variability in the distribution of multimorbidity in Italy, with worse comorbidity profiles observed in central and southern regions compared to the north, reflecting underlying socio-demographic and economic factors (Corrao et al., 2020).

In addition to somatic comorbidity, elderly HF patients face a high risk of mental comorbidity, such as depression and anxiety, which contribute to poorer health outcomes and reduced adherence to treatment regimens (Farokhnezhad Afshar et al., 2019) and might affect the outcomes of cardiac rehabilitation (Gostoli et al., 2016). Furthermore, depression in the elderly is associated with decreased mood and self-esteem, which further deteriorates their HRQoL (Wróblewska et al., 2021). In Italy, living alone, economic difficulties, and low education levels were also associated with higher rates of depressive symptoms among the elderly (Casigliani et al., 2023).

Polypharmacy, a regular use of 5 or more medications, is common among elderly HF patients with multimorbidity and is associated with increased risks of adverse outcomes, including hospitalization, frailty, and mortality (Cheung et al., 2020). A study in Emilia-Romagna region found that 39.4% of elderly individuals, including HF patients, were exposed to polypharmacy (Slabaugh et al., 2010). Polypharmacy in elderly HF patients is also associated with adverse drug reactions, increased healthcare utilization, and potentially inappropriate medication use and often people struggle to adhere to demanding treatment regimens, increasing their reliance on external self-care and assistance with daily activities. Therefore, elderly HF patients with multimorbidity have difficulties in following complex treatment plans, receiving inadequate social support, and experiencing unsuccessful medical assistance during symptom recurrence (Von Buedingen et al., 2018). All of the above contribute to reduced mobility, cognitive impairment, health anxiety, depression, and treatment non-adherence, that are further associated with a poor health-related quality of life (HRQoL).

1.2. Health-related quality of life of multimorbid elderly HF patients

HRQoL is a critical concept in healthcare. It encompasses patients' physical, mental, and social health perceptions and focuses on the impact of health status on quality of life (QoL) (Hays & Reeve, 2024) as well as guiding healthcare policies and interventions to enhance patient well-being (Hays & Reeve, 2024). HRQoL is often assessed through EQ-5D for global QoL (Herdman et al., 2011) that also includes perceived health status scale, and through the Kansas City Cardiomyopathy Questionnaire (KCCQ-12) (Spertus & Jones, 2015) for disease-specific QoL. These tools include measures of functional ability, pain, mental health, and social functioning, providing a comprehensive understanding of a patient's well-being. The former is used to identify changes in patients' health over time and the latter provides detailed insights into the patient's health status (Belkin et al., 2022).

Compared to the general population and individuals with other chronic diseases, HF patients generally experience a poorer HRQoL, which is associated with decline in both physical and psychological aspects of QoL (Mohamed et al., 2024; Park, 2022). Reduced HRQoL is influenced by various factors including sociodemographic aspects, physical and cognitive health, as well as mental well-being (Ventoulis et al., 2024). This is further associated with poor levels of health behaviors and self-rated health (Mohamed et al., 2024; Park, 2022). According to the literature, age and gender are related to poor HRQoL with older age and female gender (Ventoulis et al., 2024), reporting higher levels of depression and lower scores in both physical and emotional domains of HRQoL (Fonseca et al., 2021; Huang & Tsai, 2024). Moreover, older HF patients often see a decline in HRQoL due to the progressive nature of HF that leads to increased physical, psychological, and social limitations. According to "The Mugello study" conducted in Tuscany, women above 90 years old, despite living longer, reported poorer physical and mental health compared to men, with higher depression rates and lower scores in daily activities (Padua et al., 2018). Furthermore, the relationship between health perception and physical activity among the elderly in Italy showed that men generally exhibit higher levels of physical fitness, which is associated with better perceived QoL (Silva et al., 2021; Toselli et al., 2020).This difference could be due to various aspects, such as symptom perception, coping mechanisms, and societal roles.

Clinical factors such as the New York Heart Association (NYHA) (Dolgin & New York Heart Association Criteria Committee, 1994) functional class and ejection fraction (EF) are significant predictors of HRQoL in HF patients. Higher NYHA classes indicate more severe symptoms [**Table 1**] and are associated with a lower HRQoL. Higher NYHA class is strongly associated with lower HRQoL regardless of EF categories, where patients in the ‘worst’ category as compared with the ‘best’ have the highest risk of all-cause death (Settergren et al., 2025). However, Masoudi and colleagues (2004) reported that older patients, despite having worse NYHA classes, reported better HRQoL than younger patients, suggesting that older adults may have different expectations or coping mechanisms that influence their perception of QoL (Masoudi et al., 2004).

Table 1

New York Heart Association classification description

NYHA class	Description
I	No symptoms with everyday exertion (but demonstrable functional impairment of the heart).
II	Mild discomfort on everyday exertion and reduced performance
III	Significant reduction in performance already at low levels of exertion
IV	Resting dyspnea

Note: NYHA - New York Heart Association

According to the European Society of Cardiology (ESC) guidelines (McDonagh et al., 2021) HF is classified by EF, a percentage of blood pumped out with each contraction by the left ventricle. The classification includes reduced left ventricular ejection fraction (HFrEF; <40%); HF with a "moderately reduced" left ventricular ejection fraction (HFmrEF; 40% - 49%) and HF with preserved left ventricular ejection fraction (HFpEF; ≥50%). HF patients with HFpEF often experience worse outcomes in terms of HRQoL compared to those with HFrEF. This is due to the fact that patients with HFpEF are typically older and report a higher burden of comorbidities such as hypertension and diabetes, which are less prevalent in HFrEF (Ventoulis et al., 2024). Additionally, the symptom burden, including dyspnea and fatigue, is often more pronounced in HFpEF, further worsening HRQoL compared to HFrEF (Johansson et al., 2022). In Italy, approximately one-third of HF patients have HFpEF and its rising prevalence represents a growing concern for the healthcare system and requires urgent attention to improve patient outcomes (Almeida & Andrade, 2022; Andrea di Lenarda et al., 2024; Kapelios et al., 2023). HRQoL tends to be lower when comorbid conditions such as atrial fibrillation, diabetes metabolic syndrome, arthritis and hyperlipidemia, which are present (Manemann et al., 2024; Tran et al., 2022), impacting on HF. Furthermore, elderly HF patients aged over 80 years, who have comorbidities such as chronic kidney disease and experience symptoms like exertional dyspnea and peripheral edema, are more likely to have a lower HRQoL (Wang et al., 2022). Indeed, the symptom burden (Simou et al., 2022), that is associated with multimorbidity, in HF elderly is manifested by pain, lack of energy, and depression, which also contribute to reduced HRQoL (Eckerblad et al., 2020). Additionally, mental comorbidities also have been shown to negatively impact HRQoL in HF patients, with depression having the most substantial effect (Comín-Colet et al., 2020). Indeed, the presence of depressive symptoms in elderly HF patients is linked to lower physical and mental HRQoL scores due to its association with physical limitations and lower overall life satisfaction

(Uchmanowicz & Gobbens, 2015). Additionally, according to the literature the significant predictors of depression in elderly HF patients are also lack of social support, fatigue and poor health perception (Rababah et al., 2022). Furthermore, the emotional burden of HF, including feelings of worry and fear, is as significant as physical impairments, leading to considerable restrictions in daily routines and social life (Wehrmann et al., 2022). Such restrictions also include physical frailty and reduced physical capacity that are prevalent among older HF patients, leading to poor HRQoL and increased rehospitalization rates (Kitzman et al., 2021). In Italy, a survey conducted in a large community hospital revealed that a significant proportion of elderly HF patients, especially those with osteoarthritis (Berto et al., 2021), experience severe limitations in mobility and self-care, which are critical components of physical function (Albanese et al., 1999), that impact HRQoL (Hägglund et al., 2008). Physical function is closely linked to cognitive performance such as reaction time and memory, which also affects HRQoL (Wood et al., 1999). Cognitive impairment exacerbates the difficulties associated with self-care and adherence to treatment (Doehner et al., 2023) and negatively impacts self-efficacy, a crucial component of HRQoL, by impairing patients' capacity to manage their HF effectively (Wissel et al., 2022). Furthermore, among elderly patients with cognitive impairment poor emotional well-being and social interactions further compromise HRQoL (Hernández-Flórez et al., 2024). In addition, research indicates that being married and not living alone are protective factors to HRQoL, underscoring the importance of social ties in sustaining both physical and mental well-being (De Belvis et al., 2008). Moreover a study on older outpatients in Italy found that poor HRQoL extends beyond immediate health outcomes and predicts adverse health outcomes such as falls, emergency department admissions, nursing home placement and death (Bilotta et al., 2011; Fazio et al., 2024).

2. CHRONIC CARE FOR ELDERLY HF PATIENTS WITH MULTIMORBIDITY

Considering the complexity of health-related issues of older HF patients with multimorbidity there is a need for a holistic and person-centered approach to their healthcare that considers somatic and mental comorbidities. However, the traditional single-disease approach in healthcare systems, still often used in care for multimorbid patients, leads to insufficient and potentially harmful fragmented care (Almeida & Andrade, 2022). Effective management of HF patients with multimorbidity necessitates a multidisciplinary approach that includes individualized care plans and guideline-driven evidence-based interventions (Ho et al., 2014). Integrated care models, often based on the Chronic Care Model (CCM) (Wagner et al., 1996), identifies essential components such as self-management support, delivery system design, decision support, and clinical information systems, which collectively encourage high-quality personalized chronic disease care (Van der Vlegel-Brouwer, 2013). Such integrated care models focus on coordinated care that prioritizes patient's needs over the disease itself (Sampalli et al., 2012) and have been shown to improve outcomes by coordinating health providers, home-based care, and patient empowerment, supported by information and communication technology tools. For example, the multifaceted care model for chronic heart failure (CHF) that aligned a multidisciplinary heart care team with home/community service providers, implementing evidence-based protocols across the care continuum, resulted in improved clinical outcomes, such as reduced 30-day readmissions, and economic benefits, including decreased post-discharge inpatient and post-acute costs (Hadi et al., 2019). On the same vein, a nurse-led integrated chronic care approach has proven superior to usual care reducing cardiovascular hospitalizations and improving cost-effectiveness (Yu et al., 2024). Indeed, registered nurses in care coordination acting as a bridge between different levels of care ensure that the healthcare system is client-oriented (Thomas & While, 2007). Such intervention have been shown to significantly reduce hospital admissions and improve economic outcomes among CHD patients, emphasizing the importance of systematic follow-up care and patient education (Palmer et al., 2003). Therefore, integrated care models are beneficial for older patients with mental comorbidities and emphasize the importance of a multidisciplinary team, care coordination, individualized care planning, and self-management support, although financial aspects and service outcomes need further exploration (Tops et al., 2023).

The World Health Organization (WHO) advocates for person-centered integrated care, such a *collaborative care models*, to address the high treatment burdens and adverse health outcomes associated with multimorbidity (Wu et al., 2023), where patients often have complex health needs. These models can be particularly beneficial, since they allow for a more holistic assessment of the patient's condition, considering the interactions between different diseases and their treatments. Such collaborative comprehensive approach can help in identifying and addressing potential gaps in care, thereby improving health outcomes and reducing the burden on patients (Berntsen et al., 2018). Furthermore, collaborative care models emphasize the importance of patient involvement in decision-making as they ensure that care plans are tailored to the patients' needs and preferences (Michielsen et al., 2023). This not only enhances the quality of care but also HRQoL and promotes patient satisfaction and engagement (Katon et al., 2010), which are crucial for achieving positive health outcomes. Furthermore, the collaborative care models have been shown to improve clinical outcomes and reduce inappropriate emergency room visits by empowering self-management and enhancing the management of cardiovascular risk factors (Petrelli et al., 2021) as well as demonstrated significant improvements in self-care abilities and cardiac function among CHF patients (Hua et al., 2019).

To improve the coordination and quality of care for individuals with chronic or complex health conditions, collaborative care models often incorporate a designated healthcare provider with responsibility for care delivery such as a case or a care manager. The roles of care managers and case managers in chronic care, while overlapping in some areas, also have distinct differences [**Table 2**]. Case managers are responsible for coordinating care across various healthcare settings, ensuring that patients receive comprehensive and continuous care tailored to their specific needs with a focus on building long-term relationships with patients, which helps in overcoming barriers such as trust, self-efficacy, and complexity (Runnels et al., 2022). On the other hand, care managers usually work within a more structured framework, utilizing health information technology to manage patient-related information efficiently. In practice, care managers are seen as facilitators of clinical-therapeutic paths, supporting patients, their families, and multidisciplinary teams through an integrated interdisciplinary approach (De Luca et al., 2022). However, both case and care managers are effective in managing patients with multiple chronic conditions, as they can implement detailed clinical protocols and foster integration of care across medical providers by serving as a bridge between patients, GPs, and specialists, assisting patients in adopting suitable health behaviors, which improves clinical outcomes and reduces hospitalizations (García-Fernández et al., 2014).

Table 2

Case and care managers in chronic care

	Care Manager	**Case Manager**
Focus	Medical care and therapeutic interventions delivery.	Coordinating services and resources for patients.
Setting	Hospitals, clinics, or long-term care facilities.	Social services and health insurance offices.
Role	Ensuring that patients receive high-quality care that meets their needs, as well as assessing patients' physical, psychological, and social needs, developing care plans, coordinating services and resources, monitoring patient progress, and providing	Advocating for clients, coordinating services and resources, and helping clients navigate the complex healthcare system, including healthcare insurance.

	education and support to patients and their families.	
Background	Nurses or other healthcare providers	Social workers, psychologists or profession in other related fields such as occupational therapists, physical therapists, and nutritionists.

2.1. *Care management among multimorbid elderly with HF in Italy*

Italian healthcare system is presented with variations in the healthcare services provided across different regions due to its decentralization, with each of the 21 regions having the autonomy to manage and offer healthcare services. According to The Italian Network on Congestive Heart Failure (IN-CHF) registry (Baldasseroni et al., 2002), which has provided valuable insights into the epidemiological and clinical characteristics of HF outpatients in Italy, there is a need for continuous care and the reduction of hospital admissions, which remain a significant cost component in HF care (Fabbri et al., 2006).

Nurse-led programs such as Family and Community Nurse (IFeC) have a significant impact in addressing the evolving patients' healthcare needs, especially in the context of aging and chronic diseases (D'Onofrio, 2022). The role of the family and community nurse is to integrate hospital and primary care services, focusing on illness prevention and health promotion (Dellafiore et al., 2022; Marcadelli et al., 2019). Indeed they have demonstrated effectiveness in managing chronic conditions, including HF, reducing hospital readmissions, and detecting major cardiovascular events (Scrimaglia et al., 2024). However, despite their effectiveness, the integration of family and community nurses across the Italian National Health System remains inconsistent, with a lack of standardized implementation across Italian regions (Marcadelli et al., 2019). In Tuscany the family community nurse model has been implemented with varying degrees of success across different Local Health Authorities, focusing on transversality, proximity, continuity, and customization of care (Taddeucci et al., 2023). In Emilia-Romagna, the IFeC is part of the region's healthcare system, particularly in the context of the Community Health Centre model, known locally as “Case della Comunità” that provides an effort to shift healthcare focus from hospital-based to community and home-based services (D’Onofrio, 2022). Therefore, the role of family and community nurse is seen as a point of reference for nursing care, which is evolving towards providing new, original, and autonomous responses to the needs of the population (D’Onofrio, 2022).

HF management has been actively improving also through integrated care models that incorporate patient preferences and expectations as well as educational efforts. For instance, the APULIA HF multicenter study in Puglia region demonstrated the efficacy of a management protocol that integrates hospital and territorial health services, resulting in reduced hospitalizations and improved therapy adherence for acute decompensated HF patients (Iacoviello et al., 2017). On the same vein, the Diagnostic Therapeutic Assistance Pathway (Percorso diagnostico terapeutico assistenziale; PDTA) for HF is a structured approach implemented in Bologna, Italy (*Azienda USL di Bologna*, n.d.), designed to optimize patient care by integrating diagnostic, therapeutic, and assistance processes. The PDTA emphasizes the importance of a multidisciplinary framework, including collaboration and integration with territorial medicine, which is crucial for HF management. This approach aims to reduce hospital readmissions and improve QoL. Additionally, it ensures accurate diagnosis, tailored treatment plans, and streamlined clinical pathways, thereby enhancing drug treatment protocols.

Collaborative chronic care models also have been increasingly implemented in Italy to address the complex healthcare needs of elderly patients’ chronic diseases, including HF, particularly those with multiple comorbidities. These models emphasize a multidisciplinary approach, integrating case/care managers, GPs and other healthcare professionals to enhance patient outcomes. Among collaborative care model-based programs, in Tuscany a pilot hospital-territory disease management program was tested involving specialists, GPs, and nurses demonstrated a significant reduction in hospitalizations and emergency calls, underscoring the effectiveness of coordinated care models in managing HF (Mazzuoli et al., 2012). Another innovative approach "The Chronic Related Groups" model suggested ensuring continuity of care by predefining resource quotas for outpatient services such as outpatient consultations, therapy, home hospitalization and prosthetics (Sorlini et al., 2012). The model is intended for the systematic fulfilment of the treatment strategy with regard to the patients with such chronic diseases as obstructive pulmonary disease, hypertension, heart diseases and diabetes. Therefore it helped to provide a comprehensive care outside the hospital (Sorlini et al., 2012). In the Veneto region, a community care management program for multimorbid elderly patients with CHF involved a collaborative team-based model with GPs and nurses' participation in delivering an individualized healthcare plan addressing medications, self-monitoring, lifestyle, and treatment goals. This plan was shared with patients, caregivers, and other healthcare providers to ensure coordinated care and facilitate transitions between care settings. The program has demonstrated effectiveness in reducing hospital admissions and emergency room visits by emphasizing prevention, self-management, and continuity of care (Tiozzo et al., 2019).

The "Puglia Care" program, based on CCM, focused on chronically ill patients, included six interrelated components, including self-management support, clinical information systems, delivery system redesign, decision support, health care organization, and community resources. A care manager was assigned to each patient to coordinate communication between the patient, their family, and healthcare providers, monitor the patient's adherence to prescribed therapies, coordinate healthcare services and encourage patients to adopt a more active and healthier lifestyle. In addition, to monitor complex patients effectively, care managers were provided with the technological framework to access to update patient data, including results from laboratory tests and telemedicine devices. The model has shown a reduction in unplanned hospitalizations and associated costs, although there was an increase in costs related to planned hospitalizations and outpatient visits, reflecting changes in healthcare delivery and population aging (Robusto et al., 2018).

Another program that implemented a support figure as CM, is the “Leonardo” project conducted in the Apulia region of Italy that aimed at evaluating the impact of a disease and care management model in the primary health care system, specifically for patients with cardiovascular disease (CVD), diabetes, HF, and those at risk of CVD. CMs were trained in care management nurses integrated into the health care system to support GPs and specialists with primary goal to empower patients to take a more active role in managing their health, thereby improving health outcomes and promoting appropriate resource utilization. CMs assisted with development of individualized care plans that reflected the treatment recommendations of doctors and specialists, as well as personal health goals chosen by the patients. CMs also provided educational materials tailored to specific conditions or risk factors, assisted with service coordination, and offered regular one-on-one health coaching sessions to address individual patient concerns and goals. Additionally, CMs were responsible for care coordination, such as keeping patients informed about medical appointments, rehabilitation schemes, and behavior changes necessary for optimal health outcomes. They needed to explain diagnoses and therapeutic goals in lay terms to the patients to ensure successful completion of the care program (Ciccone et al., 2010). The project demonstrated significant efficacy in enhancing patients' health literacy, self-regulatory capabilities, and preparedness to alter health-related behaviors (Ciccone et al., 2010).

Furthermore, telemedicine integrated into collaborative chronic care models, as seen in the OPLON project in Italy, which focused on tele-monitoring and tele-assistance of patients with different needs and pathologies, is suggested to be beneficial for patients. The "Care &

Cure" model was designed to be adaptable to different risk levels and regional contexts, focusing on frail elderly patients (Rosati et al., 2017). The Maugeri Centre for Telehealth and Telecare has successfully implemented a telehealth program for chronic patients in Brescia, including those with CHF, resulting in reduced rehospitalization rates and increased patient satisfaction. The program included remote monitoring of cardiorespiratory parameters, weekly phone-calls by the nurse, and exercise program, monitored weekly by the physiotherapist (Bernocchi et al., 2018).

Despite these efforts, there are still areas that require improvement. For example, according to the VASTISSIMO study (Mureddu et al., 2019) there is a need for better detection and management of preclinical HF in outpatient clinics, as many patients with risk factors such as previous acute myocardial infarction or left ventricular hypertrophy had their risk underestimated by cardiologists. In Sicily, HF management is often based on personal initiative rather than structured protocols, with a lack of dedicated HF units and post-discharge therapy titration in many centers, suggesting the necessity for a more organized approach to improve outcomes and sustainability (Gesaro et al., 2019).

Overall, the current approaches to HF management among the elderly in Italy are constantly evolving to address the complex needs of this population. Integrated and collaborative chronic care models in Italy highlight the potential for improved management of elderly HF patients through integrated, personalized, and technology-supported approaches, addressing both clinical and organizational challenges in chronic disease management.

2.2. Blended Collaborative Care in the ESCAPE project.

The Evaluation of a patient-centered biopsychosocial blended collaborative care pathway for the treatment of multimorbid elderly patients (ESCAPE) project (EU Horizon 2020; project number 945377) introduced a blended collaborative care (BCC) approach aimed to improve the HRQoL for older multimorbid patients with HF (Zelenak et al., 2023). The

ESCAPE project consists in a randomized controlled trial designed to evaluate a patient-centered biopsychosocial care pathway, emphasizing the integration of care for elderly patients with multiple chronic conditions which was conducted across five European countries, including Italy, focusing on the evaluation of BCC in comparison to local usual care. BCC is based on Wagner’s CCM (Wagner et al., 1996) and aligns with the broader context of collaborative care models, which have been shown to improve outcomes for depression and anxiety by employing a multidisciplinary team and evidence-based care. Key components of the ESCAPE BCC intervention include: a) *regular patient contacts* by CMs to monitor symptoms, provide education about conditions, and offer support in achieving patients’ health goals; b) *integration of health behaviors* such as dietary changes, physical activity and other lifestyle modifications, into patients’ daily routines; c) *multidisciplinary clinical specialist team* to oversee the BCC intervention and ensure that the care provided adheres to the latest guidelines and addresses any barriers to treatment that may arise; d) *shared decision-making* among patients, caregivers, and healthcare providers to tailor treatment plans to the individual needs and preferences of the patient, fostering a sense of ownership and commitment to the treatment process; e) *personalized treatment plans* based on the patient's specific health needs, goals, and circumstances, ensuring that the care is both effective and feasible for the patient to follow (Zelenak et al., 2023). Moreover, the ESCAPE BCC is facilitated through an eHealth platform imergo® specifically developed for the project, which fosters integrated treatment advice tailored to individual needs and preferences, thus enhancing self-management and disease coping strategies among patients (Zelenak et al., 2023).

According to the Public Participatory Investigation (PPI) phase of the ESCAPE project that was conducted to develop quality indicators, elderly patients suffering from HF alongside somatic and psychological comorbidities have indicated a predominance of specific healthcare needs and preferences. Identified preferences were related to education pertaining to HF and its comorbidities, the active involvement of patients in their own healthcare management, enhanced communication support from CMs with healthcare professionals, monitoring of symptoms, and the provision of coordinated, regular updates regarding the progression of symptoms (Gostoli, Bernardini, et al., 2024). In addition, according to study within PPI phase among Italian patients, CMs should also consider the specific needs of elderly multimorbid HF patients, including psychological and psychosomatic distress, particularly somatization, and lower QoL, to create personalized healthcare pathway (Gostoli, Subach, et al., 2024). Alongside with addressing patients' physical and mental health challenges, BCC in Italy also provides assistance to caregivers, acknowledging their indispensable role in the healthcare journey of the patient and equipping them with resources to adeptly manage the intricate needs of the patients.

The ESCAPE study findings have the potential to serve as a model for treating multimorbidity across different healthcare systems, including Italy's, by providing adaptable recommendations and pathways for routine care. Overall, the implementation of BCC in Italy represents a promising advancement in the management of multimorbid patients, offering a structured, team-based approach that could significantly improve patient outcomes and healthcare efficiency.

2.2.1. The role of a Care Manager in the ESCAPE BCC

CM is a central figure in BCC framework that is specifically trained in care management, communication skills, shared decision-making, motivational interviewing, and problem-solving techniques. Training, provided by the ESCAPE, ensures that CMs are proactive and well-equipped to handle the complexities of patient care in a collaborative environment. CMs are responsible for maintaining regular contact with patients, typically through telephone calls, and educating patients about their conditions and treatments, monitor symptoms, and identify critical signs (i.e. 'red flags') such as angina pectoris or breathlessness.

Such ongoing interaction assists in integrating health behavior and self-management into the patient's daily routine, which is crucial for secondary prevention. In collaboration with patients, CMs set personalized goals aligned with the treatment plan confirmed with their GPs or cardiologists, for example increasing physical activity or self-monitoring weight gain. Furthermore, CMs provide support in achieving these goals and ensure that patients adhere to treatment agreements established between them and their healthcare providers. CMs also impart skills to cope with psychological burdens and encourage the use of community resources when necessary. CMs act as a bridge between patients and their healthcare providers, collecting pertinent medical information, which is then reviewed and confirmed by the patient's GP or cardiologist (Italy). This information is used to suggest a treatment plan that considers current guidelines and the patient's preferences and life goals. CMs also update GPs/cardiologists on patient progress and alert them to any concerning issues. CMs are supervised by a clinical specialist team, which may include, but is not limited to, a GP, cardiologist, pharmacist, and mental health specialist. CMs present patient cases to this team during regular meetings and discuss the recommendations with patients and their carers and the team oversees the treatment plan, assists in addressing treatment barriers, and makes guideline-based recommendations (Zelenak et al., 2023).

The benefits of care management for elderly multimorbid HF patients are well presented in the literature, but questions still remain. Indeed, despite existing research on the topic, some aspects of multimorbid elderly HF patients' profiles need to be identified and understood more comprehensively. Furthermore, there has not been sufficient focus on CMs' perceptions of their role in the elderly multimorbid HF patients' care, as specified in the ESCAPE guidelines. By gaining a better understanding of these perceptions considering the ESCAPE methodological procedure and demands, it is believed that the model of care could be improved, and CMs' role could be tailored to enhance the overall care model. Based on these premises, the current research is divided into two studies. The first study (*see Chapter 3*) aimed to explore and better understand the unique characteristics of elderly multimorbid HF outpatients, consecutively recruited by the ESCAPE project at the Bellaria Hospital in Bologna between September 2022 and August 2024. The second study (*see Chapter 4*) was focused on CMs' perception on their role within the ESCAPE BCC framework and how it could be tailored and effectively integrated into the local healthcare system.

3. ELDERLY MULTIMORBID HEART FAILURE PATIENTS' HEALTH-RELATED QUALITY OF LIFE EXPLORATION

3.1. Aims and objectives

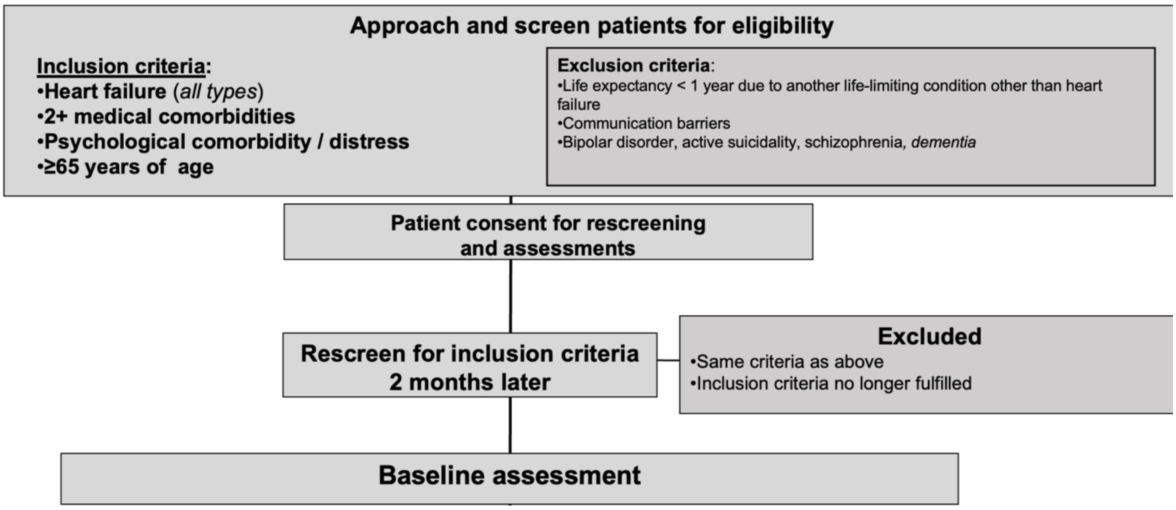
The aim of this exploratory descriptive cross-sectional study was to detect the impact of sociodemographic, clinical, psychosocial and psychological characteristics on perceived health status, global and disease-specific QoL among elderly HF patients with multimorbidity, who have been recruited for the BCC intervention within the ESCAPE project at Bellaria Hospital in Italy.

3.2. Participants and procedures

Recruitment took place at Bellaria Hospital in Bologna (Italy) following the ESCAPE recruitment procedure (Zelenak et al., 2023). The process included initial screening and a follow-up screening around two months later, where participants were re-evaluated according to the same inclusion and exclusion criteria [**Figure 1**]. Eligible patients underwent comprehensive assessment [see **Appendix 1; Table 1**]. Patients were required to provide written consent to participate in the study. Inclusion criteria include the following: a) age ≥ 65 years; b) physician-diagnosed chronic HF; c) two or more medical comorbidities; d) elevated psychological distress (Hospital Anxiety and Depression Scale (HADS) total score >12 detecting at least mild levels of distress and/or diagnosed mental disorder(s). Exclusion criteria regard: a) life expectancy <1 year due to causes other than HF; b) communication barriers (e.g., no telephone, severe hearing impairment, inability to speak, read and understand the language of the country of recruitment); c) severe mental disorder needing specific psychiatric treatment and / or interfering with the study treatment, e.g., bipolar disorder, active suicidality, schizophrenia, severe dementia (the data will be collected through medical record/letter from a hospital); d) permanently living in a nursing home; e) being permanently bedridden.

Figure 1

A flow chart of the ESCAPE project recruitment process.



3.3. Assessments

The data utilized in the current study was obtained from the ESCAPE project funded by Horizon 2020 (project number 945377), which was approved by the Comitato Etico di Area Vasta Emilia Centro (CE-AVEC) at Sant'Orsola-Malpighi Polyclinic, University of Bologna ("Azienda Ospedaliero-Universitaria di Bologna, Policlinico S. Orsola-Malpighi", Protocol N. PG0012699/2021) (Zelenak et al., 2023). The data collection process was conducted in accordance with the ESCAPE project's protocol. Available baseline data pertaining to Italian patients recruited at Bellaria Hospital in Bologna was used for the analysis. Elderly HF patients scheduled for their outpatient visit at the heart failure, valve disease or atrial fibrillation outpatient's clinic at the Cardiology department of Bellaria Hospital were introduced to the ESCAPE project and invited to participate. All patients provided written consent prior assessments. Those who consented underwent an initial screening to assess their eligibility for the study. Patients who met the eligibility criteria were then invited for a re-screening approximately two months later to confirm inclusion of individuals with persistent psychological distress (HADs score > 12). Those who continued to meet the eligibility criteria during the re-screening were subsequently invited for the baseline assessment.

Detailed patient interviews and available medical records were used to collect sociodemographic (i.e., age, gender, marital status, living condition, occupation, level of education) and medical information (i.e., diagnosis, systolic function - EF, NYHA class, medical conditions, prescribed medications, cardiac interventions and symptoms such as sleep disturbance, concentration problems, dry mouth, other pain than chest ache, palpitations or irregular heartbeats, itch and neurological problems).

The patients' reported outcomes covering specific areas of functioning, activity, medical adherence, stress, treatment burden, illness perception, loneliness, perceived emotional support, spiritual well-being, as well as psychological distress, depressive symptoms and QoL were collected through a variety of standardized and validated self-rating instruments.

3.3.1. Global and disease specific quality of life

HRQoL assessment included global QoL that also includes perceived health status scale and disease specific QoL. The EuroQoL 5 Dimension 5 Level (*EQ-5D-5L)* was used to assess global QoL (Herdman et al., 2011; Janssen et al., 2013). It is a standardized instrument for measuring HRQoL. It consists of five dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each dimension has five levels of response and is scored from 1 (no problem) to 5 (unable to/extreme problems). A single summary index is calculated using population-specific value sets (Meregaglia et al., 2023). The EQ-5D-5L has been validated in Italy (Meregaglia et al., 2023). It has demonstrated good construct validity, responsiveness, and reliability. It was used in numerous studies including multimorbid (Mercer et al., 2016) and elderly populations (Ten Haaf et al., 2018). EQ-5D-5L also include a visual analogue scale (EQ-VAS) (Ten Haaf et al., 2018) to measure the perceived health status (0 - 100) with endpoints labelled as 'The best health you can imagine' (100) and 'The worst health you can imagine'(0).

Short version of the Kansas City Cardiomyopathy Questionnaire (KCCQ-12) with 12 items was validated and used to assess disease specific QoL aspects specifically related to living with HF (Spertus & Jones, 2015). Each item is scored on a Likert scale, and a total score is calculated. Higher scores indicate better health status with cut-off point of 75 or higher indicating good-to-excellent disease specific QoL (Spertus et al., 2020). The KCCQ-12 has been validated in multiple languages and populations, including Italian. It has demonstrated good internal consistency, test-retest reliability, and construct validity (Miani et al., 2003).

3.3.2. Psychological distress and depressive symptoms

The Hospital Anxiety and Depression Scale (HADS) is a 14-item instrument designed to assess anxiety and depression in patients (Zigmond & Snaith, 1983). The scale consists of two subscales: one for anxiety and one for depression, each containing 7 items. Each item is scored on a 4-point Likert scale, and subscale scores are calculated by summing the individual item scores. Higher scores indicate greater levels of anxiety or depression with cut-off point above 12 indicating presence of psychological distress (Zelenak et al., 2023). The HADS has been validated in various languages and populations, including cardiac patients (Poole & Morgan, 2006). It has demonstrated good internal consistency, test-retest reliability, and construct validity.

The Patient Health Questionnaire-4 (PHQ-4) is a validated brief screener used to assess depressive and anxiety symptoms (Kroenke et al., 2009). It consists of 4 items that combines the Patient Health Questionnaire-2 (PHQ-2) and the Generalized Anxiety Disorder-2 (GAD-2) each scored on a 4-point Likert scale. A total score ranges from 0 to 12 and is calculated by summing the individual item scores with 0 indicating ‘no distress’ and 12 indicating ‘severe distress’ with cut-off point of 3 and above suggesting distress (Kroenke et al., 2009). The Italian PHQ-4 version showed a good diagnostic feature for measuring depression and anxiety in CVD patients. It has demonstrated good internal consistency, test-retest reliability and construct validity (Giuliani et al., 2021).

3.3.3. Adherence, physical and cognitive status

Medication Adherence Report Scale MARS-5 (Chan et al., 2020), a 5-item instrument to elicit patients' reports of non-adherence with medical treatment recommendations. It assesses the extent to which patients take their medications as prescribed. Each item is scored on a 5-point Likert scale, with responses ranging from "always" to "never." The total score is calculated by summing the individual item scores. Higher scores indicate better adherence to medication with a cut-off point of 24 and above (Chan et al., 2020; Jožef et al., 2024). It has been validated in multiple languages, including Italian (Scribano et al., 2019), and in multiple populations, including hypertensive patients (Chan et al., 2020).

30 second chair stand test (30s-CST) was used to asses physical function (Dobson et al., 2012). It measures the number of times an individual can stand up from a seated position and return to a seated position within 30 seconds. Participants were instructed to fold their arms across their chest and stand up from a chair without assistance. A modified version of the test was used, allowing patients to use armchairs for support if necessary. The test is timed for 30 seconds, and the number of complete stands (up and down) was counted. Higher scores indicate better lower body strength and functional mobility. The 30s-CST has been extensively validated in multiple populations, including cardiac patients (Kobayashi et al., 2024; Wang et al., 2022).

PROMIS (Patient-Reported Outcomes Measurement Information System) Physical Function Short Form 4a supplemented 30s-CST test as recommended by the International Consortium for Health Outcomes Measurement (ICHOM) (Dobson et al., 2012). The PROMIS is a brief 4-item self-report questionnaire designed to assess an individual's physical function (Rose et al., 2008). The test consists of four items that assess different aspects of physical capability, such as the ability to walk, climb stairs, and perform daily activities. Each item is scored on a 5-point Likert scale, and a total score is calculated. Higher scores indicate better physical capability. It has previously been used in patients affected by chronic conditions, including HF (Kobayashi et al., 2024).

IPAQ-E (International Physical Activity Questionnaire - Elderly). Physical activity was measured using the brief 4-item version of the International Physical Activity Questionnaire for the elderly (Anita et al., 2010). The IPAQ-E is a self-administered questionnaire designed to measure physical activity in older adults. It has been validated in Italian language (Mannocci et al., 2010) and in cardiac patients (Pfaeffli et al., 2013). It assesses the frequency and duration of moderate and vigorous physical activity, as well as walking and sitting time. Physical activity levels are categorized as low, moderate, or high based on the total metabolic equivalent (MET) minutes per week.

Self-reported frailty was used for frailty status assessment. Frailty is a clinical syndrome characterized by decreased reserves and resistance to stressors, resulting in increased vulnerability to adverse outcomes. Self-reported frailty components which are conceptually designed after the established Fried Frailty Phenotype (Fried et al., 2001), was administered via mail and have good prognostic value for disability, falls, and all-cause mortality (Papachristou et al., 2017). Patients were classified into non-frail, pre-frail, and frail individual according to this criterion. It is used in elderly patients and was also translated into Italian language (Abete et al., 2017).

The 15-item blind Montreal Cognitive Assessment (MoCA) version 8.1 was used in telephone screening for cognitive impairment (Nasreddine et al., 2005). The test is scored out of 15 points, with each item contributing to the total score. Higher scores indicate better cognitive function with cut-off points as follows: mild/normal (score 18 and above), moderate (score 10-17) and severe (score below 10) (*Moca Cognition*, n.d.). It has been validated in various populations, including cardiac patients (Webb et al., 2014) and it was also translated into Italian language (Pirani et al., 2022) and has shown good reliability and validity in detecting mild cognitive impairment. This assessment was supplemented by a set of two questions assessing subjective memory decline (Luck et al., 2015).

3.3.4. Stress and treatment burden

Perceived Stress Scale (PSS-4) is a 4-item short version of the well-established scale for measuring perceived stress (Cohen et al., 1983; Ingram et al., 2016). Each item is scored on a 5-point Likert scale, and a total score is calculated. Higher scores indicate higher perceived stress using median value of PSS-4 as a cut-off point. The PSS-4 has been validated in multiple languages, including Italian (Mondo et al., 2021) and in different populations, such as cardiac patients (Leung et al., 2010; Malik et al., 2022). It has demonstrated good internal consistency and construct validity (Mondo et al., 2021).

Multimorbidity Treatment Burden Questionnaire (MTBQ) 10-item version of the Mindfulness-Based Therapy Questionnaire (MBTQ) that was used to measure multimorbidity treatment burden (Duncan et al., 2018). Each item is scored on a 6-point Likert scale, and a total score is calculated with cut-off values indicated as follows: no burden (score 0), low burden (score less than 10), medium burden (10–21) high burden (above 21). It demonstrated good content validity, construct validity and internal consistency reliability (Duncan et al., 2018).

3.3.5. Illness perception, resources & loneliness

The Illness Perception Questionnaire (IPQ-Brief) is a psychometric instrument used to assess an individual's perceptions of their illness (Broadbent et al., 2006). The 9-item version is a concise adaptation of the original IPQ, designed to quickly evaluate key dimensions of illness perception, such as identity, timeline, consequences, and control. Each item is scored on a 5-point Likert scale, ranging from "strongly disagree" to "strongly agree." A total score is calculated by summing the scores of all nine items, with higher scores indicating a more negative perception of the illness with cut-off values as follows: less than 42 indicating low experienced threat, 42-49 inducating moderate experienced threat, and 50 and above indicating high experienced threat (Kuiper et al., 2022). It has been validated in various patients' populations (Broadbent et al., 2006), including Italian patients (Pain et al., 2006).

The Patient Acceptable Symptom State (PASS) was assessed using two customized questions designed to determine whether patients were satisfied with their overall state of health (Tubach et al., 2007). These questions were developed to capture the patient's subjective perception of their health status. Responses were scored on a binary scale (yes/no), and the results were used to evaluate the proportion of patients who considered their symptom state as acceptable. It has been validated in various patients' populations (Khor et al., 2021) including Italian patients (Conti et al., 2013).

General Self-Efficacy Scale in a 6-item short form to assess self-efficacy (Romppel et al., 2013). Each item is scored on a 4-point Likert scale, ranging from "not at all true" to "exactly true." A total score is calculated by summing the scores of all items, with higher scores indicating higher levels of self-efficacy. It has been validated in cardiac patients (Kavradim et al., 2020) as well as in Italian population (Guazzini et al., 2022).

ENRICHD Social Support Inventory (ESSI) was used to measure perceived emotional social support (ENRICHD Investigators, 2001; Vaglio et al., 2004). The instrument is often used in research and clinical settings to assess the level of support individuals receive from their social networks. The ESSI consists of seven items, each scored on a 5-point Likert scale, ranging from "none of the time" to "all of the time." A total score is calculated by summing the scores of all items, with higher scores indicating greater perceived social support. A cut-off point of 18 or above indicating low social support (ENRICHD Investigators, 2001). It has been validated in cardiac patients (Vaglio et al., 2004).

The BRIEF (Brief Rapid Estimate of Adult Literacy in Medicine) Health Literacy Screening was used to assess individual's health literacy level (Haun et al., 2012). Health literacy refers to the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions. The 4-item version is a concise adaptation of the original BRIEF scale. Each item is worth of 1 to 5 points depending on response (1 – "always"; 5- "never"), and a total score is calculated by summing the scores of all four items. Higher scores indicate better health literacy with cut-off values as follows: limited (score 4-12), marginal (score 13-16) and adequate 17 and above (Haun et al., 2012). It is a useful tool for identifying individuals who may need additional support to understand and navigate health information and services. The BRIEF is widely used in clinical practice but has not been validated in cardiac patients.

UCLA Loneliness 3-item Scale is a psychometric instrument used to assess an individual's subjective feelings of loneliness and social isolation (Hughes et al., 2004). Each item is scored on a 3-point Likert scale, with responses typically ranging from "hardly ever" to "often." A total score is calculated by summing the scores of all three items. A higher score indicating greater loneliness with cut-off point above 6. It has been validated in various populations, including elderly (Russell, 1996) and Italian patients (Boffo, 2012).

The FACIT (Functional Assessment of Chronic Illness Therapy) Sp-12 Scale is a self-report questionnaire designed to assess spiritual well-being in individuals with chronic illnesses

(Webster et al., 2003). It is part of the FACIT measurement system, which includes various scales to measure different aspects of health-related QoL. The FACIT Sp-12 Scale consists of 12 items, each scored on a 5-point Likert scale ranging from "not at all" to "very much." A total score is calculated by summing the scores of all items. Higher scores indicating greater spiritual well-being with a cut-off point 36 and above (*FACIT-Sp-12*, n.d.). It has been validated in cardiac patient group, including HF patients (Deng et al., 2021).

3.4. Data analysis

Data were analyzed using JAMOVI 2.3 (Romppel et al., 2013) software. Descriptive analysis was performed on the total sample and presented as frequencies and means (± *SD*). Non-responses were not considered for statistical purposes with only complete data considered to ensure data consistency and validity. The exclusion was not expected to bias the results. Fisher exact test, applied to contingency tables, was used to compare HRQoL with a) sociodemographic characteristics, such as gender, age (e.g., 65-74; ≥ 75), marital status, living condition, education, as well a major conflicts in life, sufficient support, contact with friends, and communication tools use; b) clinical characteristics, including NYHA class, EF (e.g., <40%, 41-49% and >50%, based on the latest EF classification according to ESC guidelines (McDonagh et al., 2021), number of years with cardiac disease (with cut off ≤5 versus >5 based on the mean illness duration), co-existing diseases (with cut off ≤14 versus >14 based on the mean number of reported co-existing disorders), prescribed medications (with cut off <5 versus 5-11 and ≥12 based on polypharmacy definition identified as use of 5+ medications [(Guillot et al., 2020)] and sample average number of medications) and type of cardiac interventions; c) medical adherence, physical and cognitive status; d) illness perception, loneliness, including perceived emotional support, spiritual well-being and health literacy; e) psychological characteristics, including depression, anxiety, stress and treatment burden. To assess the impact of clinical characteristics and psychological distress on HRQoL, U Mann-Whitney tests was employed. Significance level was set at 0.05.

3.5. Results

3.5.1. Sociodemographic and clinical characteristics of the sample

Sociodemographic and clinical characteristics of the sample were reported in **Table 3**. The sample consisted of 33 individuals, with a mean age of 77.6 years (SD± 6.80), and more than half (61%) were 75 years or older. Gender distribution of the sample was nearly balanced, with 52% male participants. According to marital status, 69.7% was married and living with a partner. All participants (100%) were retired and 51.5% residing in urban areas. Regarding education, 36.4% had attended middle school, 27.3% had completed high school, and 9.1% held a university degree.

Social interactions and support were also documented. More than a half of the sample reported having little contact with friends (69.7%), and 81.8% felt they receive sufficient support from those they live with. The majority of the sample reported lack of major conflicts in life (84.8%). Communication means varied, with 78.8% using phones, 48.5% using smartphones and the internet, 36.4% using cell phones and SMS, and only 24.2% were using computers.

Regarding physical status, 43.8% engaged in low activity and 37.5% in moderate activity. 68.8% were classified as frail and 67.7% of the sample reported worse than average fatigue. Cognitive impairment of the sample, assessed with MoCa test version 8.1 (Nasreddine et al., 2005), was mostly mild/normal (46.9%). Subjective memory decline was reported by 60.3% of the sample, with 65% expressing concern about their memory worsening. Satisfaction with health was affirmed only by 6.1% of the patients, while 54.5% were partly satisfied. Medication adherence was mainly low in the sample (57.6%).

The sample presented a mean of 5.2 (range 1 - 29) years of cardiac disease duration, with 67.9% with 5 or less years. Half (52.2%) had NYHA II class and was presented with HFpEF (56.7%). Almost a half of the sample (42.4%) had more than 14 co-existing diseases. The most presented condition was high blood pressure (90.9%), followed by heart valve disease and spine or disc-related disease, each affecting 81.8% of the sample. Joint problems due to degeneration were presented by 75.8%, and 72.7% had vision or eye diseases. Other notable conditions included dyslipidemia (66.7%), atrial fibrillation/flutter (54.5%), and neurological diseases (54.5%). Regarding cardiac interventions, 51.7% of the sample underwent coronography and 24.1% received heart valve treatment. In addition, most presented symptoms were sleep disturbance and concentration problems (72.7%), followed by dry mouth and other than chest pain, each affecting 69.7% of the sample. Irregular heartbeats were presented by 54.5% and itch by 45.5%. Lastly, neurological problems were presented by 33.3% of the sample. 50% of the sample was prescribed with 12 or more medications.

Table 3

Sociodemographic and clinical characteristics of the sample (N=33)

Sociodemographic and clinical characteristics	N (%)	Mean ± SD
Age		77.6 ± 6.80
65-74	13 (39)	
≥75	20 (61)	
Gender		
Male	17 (52)	
Female	16 (48)	
BMI[1,2]		
Underweight	2 (6.9)	
Normal weight	7 (24.1)	
Pre-obesity	12 (27.6)	
Obesity	8 (27.6)	
Marital status		
Married	23 (69.7)	
Widow/widower	7 (21.2)	
Divorced	2 (6.1)	
Living condition		
Retired[3]	32 (100)	
Living with partner	23 (69.7)	

Living alone	6 (18.2)	
Living with family	9 (27.3)	
Urban area	17 (51.5)	
Education		
Elementary school	9 (27.3)	
Lower secondary school / middle school	12 (36.4)	
High school	9 (27.3)	
Higer education / University degree	3 (9.1)	
Contacts with friends		
A lot	7 (21.2)	
Average	3 (9.1)	
Little	23 (69.7)	
Sufficient support from people living with	27 (81.8)	
No major conflicts in life	28 (84.8)	
Means of communication		
Phone	26 (78.8)	
Computer	8 (24.2)	
Cell phone and SMS	12 (36.4)	
Smartphone and Internet	16 (48.5)	
Comorbidities		14 ± 3.3
≤14	19 (57.6)	
>14	14 (42.4)	
Height (cm)[2]		158 ± 40.5
Weight (kg)		79.2 ± 20.4
Years with cardiac disease		5.2 ± 6.05
≤5	19 (67.9)	
>5	9 (32.1)	
NYHA Class[4]		
Class I	3 (13)	
Class II	12 (52.2)	
Class III	8 (34.8)	
Class IV	0 (0)	
Ejection fraction[5]		
Low	6 (20)	
Mid-range	7 (23.3)	
Preserved	17 (56.7)	
Medications[5]		12.6 ± 5.2
<5	0 (0)	
5-11	15 (50)	
≥12	15 (50)	
Medical conditions		
High blood pressure	30 (90.9)	
Heart valve disease	27 (81.8)	
Spine or disc-related disease	27 (81.8)	
Joint problems due to degeneration	25 (75.8)	
Problems with vision/eye disease	24 (72.7)	
Dyslipidaemia	22 (66.7)	
Atrial fibrillation/flutter	18 (54.5)	
Neurological diseases	18 (54.5)	
Problems with hearing/ear-nose-throat disease	18 (54.5)	

Coronary artery disease	17 (51.5)
Thyroid disease	16 (48.5)
History of COVID-19 infection	16 (48.5)
Kidney disease	15(45.5)
Cardiac interventions[2]	
Coronography	15 (51.7)
By-pass surgery	2 (6.9)
Heart valve treatment	7 (24.1)
Pacemaker	3 (10.3)
Defibrillator[6]	2 (7.4)
Symptoms	
Sleep disturbance	24 (72.7)
Concentration problems	24 (72.7)
Dry mouth	23 (69.7)
Other pain than chest pain	23 (69.7)
Palpitations/irregular heartbeats	18 (54.5)
Itch	15 (45.5)
Neurological problems	11 (33.3)

Note: 1-Body Mass Index by WHO; 2-These data were calculated on sample N=29, due to missing data; 3-These data were calculated on sample N=32, due to missing data; 4-These data were calculated on sample N=23, due to missing data; 5-These data were calculated on sample N=30, due to missing data; 6-These data were calculated on sample N=27, due to missing data.

3.5.2. QoL, areas of functioning, activity, well-being and psychological characteristics

QoL, resources and prevalence of psychological distress of the sample were reported in **Table 4**. More than half of the sample (51.5%) reported a good self-reported QoL with 60.6% of perceived health status as high.

A larger portion (45.5%) rated disease-specific QoL as fair to good. Depression and anxiety levels showed that 75.8% of the sample experienced overall psychological distress, with 45.5% specifically experiencing depression and 54.5% experiencing anxiety. A clear majority of the sample had mild depression symptoms (60.6%). Perceived stress was high in 72.7% of the sample. An equal proportion of people, 39.4% of respondents, reported having either a high or low perception of their illness, indicating experienced by patient illness-related threat.

Limited health literacy was reported by 48.5% of the sample. Loneliness was reported by 54.5% of the sample and a significant portion, 63.6%, reported a lack of perceived emotional social support. Meaning and spirituality were low in 93.9% of the sample. Finally, treatment burden was high in 57.6% of the sample.

Table 4

Psychological and areas of functioning, activity, well-being and QoL (N=33)

Psychological and areas of functioning, activity, well-being and QoL	**N (%)**
Medical adherence, physical and cognitive status	
Medication adherence	
High	14 (42.4)
Low	19 (57.6)
Physical function	
Normal	12 (85.7)
Modified	2 (14.3)
Physical capability	
Worse than average	22 (67.7)
Better than average	11 (33.3)
Physical activity	
Low	14 (43.8)
Moderate	12 (37.5)
High	6 (18.8)
Frailty	
Pre-frail	10 (31.3)
Frail	22 (68.8)
Cognitive impairment	
Severe	3 (9.4)
Moderate	14 (43.8)
Mild/Normal	15 (46.9)
Subjective memory decline	
Memory is getting worse	20 (60.3)
Concerned about memory worsening[1]	13 (65)
Illness perception, loneliness and resources	
Illness perception	
High threat	13 (39.4)
Moderate threat	7 (21.2)
Low thread	13 (39.4)
Health satisfaction	
Yes	2 (6.1)
Partly	18 (54.5)
No	13 (39.4)
Treatment is not working properly[2]	9 (29)
Lack of perceived emotional social support	21 (63.6)
Meaning and spirituality	

High	2 (6.1)
Low	31 (93.9)
Loneliness	
Lonely	18 (54.5)
Not lonely	15 (45.5)
Health Literacy	
Adequate	5 (15.2)
Limited	16 (48.5)
Marginal	12 (36.4)
Psychological variables	
Psychological distress	
Yes	25 (75.8)
No	8 (24.2)
Depression	
No	18(54.5)
Yes	15 (45.5)
Anxiety	
No	15 (45.5)
Yes	18 (54.5)
Depression symptoms	
Normal	4 (12.1)
Mild	20 (60.6)
Moderate	5 (15.2)
Severe	4 (12.1)
Perceived stress	
High	24 (72.7)
Low	9 (27.3)
Treatment burden	
None	1 (3)
Low	8 (24.2)
Medium	5 (15.2)
High	19 (57.6)
Health-related QoL	
Global QoL	
Low self-reported QoL	16 (48.5)
Good self-reported QoL	17 (51.5)
Overall health status	
Low perceived health status	13 (39.4)
High perceived health status	20 (60.6)
Disease-specific QoL	
Good to excellent	4 (12.1)
Fair to good	15 (45.5)
Poor to fair	11 (33.3)
Very poor	3 (9.1)

Note: QoL – quality of life; 1-These data were calculated on a sample who replied “yes” for perceived memory decline question (N= 20); 2-These data were calculated on a sample who replied “no” for perceived health satisfaction (N=13).

3.5.3. Associations between HRQoL and sociodemographic factors

No significant associations between HRQoL and sociodemographic characteristics were found, whereas a significance association between communication tools use and disease specific QoL was found (*p* = .017) [**Table 5**]. More specifically, 75.5% of the sample did not use computer, and almost a half among them reported poor disease specific QoL.

Table 5

Disease specific QoL and communication tools use (N=33)

Communication tools	Disease specific QoL Good to excellent N (%)	Fair to good N (%)	Poor to fair N (%)	Very poor N (%)	*p* value
Phone use					.540
Yes	4 (100)	10 (66.7)	9 (81.8)	3 (100)	
No	0 (0)	5 (33.3)	2 (18.2)	0 (0)	
Computer use					.017*
Yes	0 (0)	7 (46.7)	0 (0)	1 (33)	
No	4 (100)	8 (53.3)	11 (100)	2 (66.7)	
Cellular and SMS use					.378
Yes	3 (75)	4 (26.7)	4 (36.4)	1 (33.3)	
No	1 (25)	11 (73.3)	7 (63.6)	2 (66.7)	
Smartphone and Internet use					1.000
Yes	2 (50)	7 (46.7)	5 (45.5)	2 (66.7)	
No	2 (50)	8 (53.3)	6 (54.5)	1 (33.3)	

Note: **p* value < .05

3.5.4. Associations between HRQoL and clinical characteristics, adherence, physical, cognitive status

No significant associations between HRQoL and EF, number of co-existing diseases, prescribed medications and type of cardiac interventions were reported. However, there was a significant association between disease-specific QoL and NYHA class (*p* = .020), as well as between overall reported health status and the number of years with cardiac disease (*p* = .035). [**Appendix 2, Table 1**]. More specifically, 83.3% of the patients reported high overall health status having ≤ 5 years of cardiac disease and good to fair disease specific QoL (83.3%) with I-II NYHA class. Furthermore, there were significant associations between physical capability and global QoL (*p* = .002), disease specific QoL (*p* = .022) and overall health status (*p* < .001). The majority of patients reported worse than average physical capability and associated with it low overall health status, negative global QoL and fair disease specific QoL. A significant association was found between global QoL and physical function (*p* = .033) of the sample. Patients with normal physical function (100%) had positive global QoL. In addition, frail patients (91.7%) were associated with high overall health status (*p* = .050). Lastly, patients with moderate cognitive impartment (66.7%) associated with positive global QoL (*p* = .042) [**Appendix 2, Table 2**].

3.5.5. Associations between HRQoL and illness perception, loneliness and resources

No significant associations were found between global and disease specific QoL and illness perception, loneliness and resources. A significant association was found between overall health status and illness perception (*p* = .015). More specifically, patients who experience high illness related threat had low overall health status (69.2%) [**Appendix 2, Table 3**].

3.5.6. Associations between HRQoL and psychological characteristics

No significant associations were found between global QoL and psychological characteristics of the sample. A significant association was instead found between disease specific QoL and anxiety (*p* = .005), where patients with anxiety presented with poor disease specific QoL (81.8%). Also, a significant association was found between overall health status and depression (*p* = .005), as well as with depressive symptoms (*p* =.034). Patient with depression reported low overall health status (76.9%) and those patients with mild depressive symptoms reported high overall health status (80%) [**Appendix 2, Table 4**].

3.5.7. Differences in HRQoL based on sociodemographic and clinical characteristics

No significant difference was observed concerning sociodemographic characteristics. However significant results were found regarding disease specific QoL with clinical characteristics, where lower NYHA class (I-II) was related to better disease specific QoL (*p* = .007). Also, patients with 14 or more co-existing diseases (*p* = .017) and those with an implanted pacemaker (*p* = .041) experienced a significantly lower overall health status [**Table 6**].

Table 6

U Mann-Whitney test: Health related QoL and clinical data (N=33)

Clinical characteristics	**Global QoL**		**Overall health status**		**Disease specific QoL**	
	Mean	***p* value**	**Mean**	***p* value**	**Mean**	***p* value**
NYHA[1]		.056		.176		.007
I -II	0.687		54.067		64.063	
III-IV	0.431		45.000		43.948	
Years with cardiac disease[2]		.699		.077		.730
>5	0.512		41.667		50.522	
≤5	0.591		50.842		54.313	
Number of co-existing diseases		.065		.017*		.161
≤14	0.656		52.684		56.141	
>14	0.402		39.286		48.339	
Number of prescribed medications		.367		.983		.171
5-11	0.617		47.400		58.265	
≥12	0.473		46.000		46.505	
Coronography[3]		.652		.982		.896
Yes	0.583		46.333		51.945	
No	0.519		46.857		53.175	
Bypass surgery[3]		.596		.599		.576
Yes	0.686		42.500		46.615	
No	0.542		46.889		52.987	
Heart valve treatment[3]		.784		.500		.610
Yes	0.554		42.286		55.880	
No	0.551		47.955		51.478	
Pacemaker[3]		.937		.041*		.431
Yes	0.597		63.667		61.287	
No	0.547		44.615		51.530	
Defibrillator[3]		1.000		.240		.890
Yes	0.611		60.000		55.990	
No	0.549		45.640		52.008	

Note: 1- These data were calculated on sample of N=23 due to missing data; 2- These data were calculated on sample of N=28 due to missing data; 3- These data were calculated on sample of N=29 due to missing data; 4- These data were calculated on a sample of N=27 due to missing data; **p* value < .05

3.5.8. Differences in HRQoL based on medical adherence, physical and cognitive status difference on HRQoL

The analysis indicated that patients with frailty had lower global QoL (*p*= .022), poorer overall health status (*p*= .031), and reduced disease-specific QoL (*p*< .001). Furthermore, analysis revealed significant differences between patients' physical capability and global QoL (*p*< .001), overall health status (*p*= .049), as well as disease-specific QoL (*p*< .001). Lastly, physical function had a significant impact on global QoL (*p*= .022) [**Table 7**].

Table 7

U Mann-Whitney test: Health related QoL and medical adherence, physical and cognitive status

Adherence, physical and cognitive status	**Global QoL**		**Overall health status**		**Disease specific QoL**	
	Mean	**P value**	**Mean**	**P value**	**Mean**	**P value**
Medical adherence		.900		.724		.799
Highly adherent	0.583		46.500		53.386	
Partly adherent	0.523		47.368		52.422	
Physical function[1]		.022*		1.000		1.000
Normal	0.793		55.000		66.711	
Not normal	0.449		53.000		64.585	
Physical capability		<.001**		.049		<.001**
Worse than average	0.415		43.227		43.663	
Better than average	0.815		54.545		71.166	
Frailty						
Pre-frail	0.732	.022*	56.600	.031*	71.880	<.001**
Frail	0.475		43.182		43.284	
Subjective memory decline		.986		.337		.868
Yes	0.534		44.750		51.312	
No	0.570		50.462		55.168	

Note: 1- These data were calculated on sample of N=14 due to missing data; **p* value < .05; ***p* value < .001

3.5.9. Differences in HRQoL based on psychological characteristics

The results indicated that depressed patients had lower global QoL (*p*= .002), poorer overall health status (*p*= .010), and reduced disease-specific QoL (*p*= .026). Further, the results indicated that patients with anxiety had lower global (*p*= .005) and reduced disease-specific (*p*= .006) QoL. Lastly, psychological distress showed significant only with disease specific

QoL (*p*= .005) among the sample, indicating a specific influence of psychological distress on the QoL related to the disease condition [**Table 8**].

Table 8

U Mann-Whitney test: health related QoL and psychological characteristics

Psychological characteristics	**Global QoL**		**Overall health status**		**Disease specific QoL**	
	Mean	***p* value**	**Mean**	***p* value**	**Mean**	***p* value**
Psychological distress (HADs)		.127		.534		.005*
No	0.501		46.000		46.674	
Yes	0.697		50.125		72.072	
Anxiety (HADS -A)		.005*		.150		.006*
No	0.712		51.400		64.376	
Yes	0.412		43.333		43.210	
Depression (HADS-D)		.002*		.010*		.026*
No	0.666		53.111		61.504	
Yes	0.407		39.667		42.936	
Perceived stress		.706		.934		.284
High	0.552		47.333		56.316	
Low	0.539		46.111		43.537	

Note: **p* value < .05

3.6. Discussion

The current study revealed that sociodemographic factors are not significantly associated with perceived health status, disease specific and global QoL among elderly HF patients with multimorbidity. The results contrast with research conducted by Heidenreich and colleagues (2016), who suggested that older age and female gender are associated with poorer HRQoL (Heidenreich, 2016). However, according to Moser and colleagues (2013), older HF patients could report better HRQoL compared to younger ones, despite having worse physical health because they might have adjusted expectations regarding their health and QoL (Moser et al., 2013). Therefore, the results may be attributed to the fact that the current sample is predominantly older, with 61% of participants aged above 74 years.

Furthermore, the majority of the sample consisted of individuals who were married or living with a partner which, according to the literature, is generally associated with higher life satisfaction and better HRQoL. Being married is often associated with better social support and continuity in social engagement, which are crucial for mental and physical well-being in older age (Gutiérrez-Vega et al., 2018). The significant difference in disease specific QoL and computer use among elderly individuals with HF was found in the study. Indeed, the integration of digital technologies into the daily lives of older adults has shown potential benefits, including enhanced cognitive functions, improved social connectivity and access to information (Aggarwal et al., 2020). The Internet provides older adults with access to a wealth of information, including health-related content, which can empower them to manage their health conditions more effectively (Vidiasratri & Bath, 2022).

Regarding clinical characteristics, NYHA class was significantly associated with disease-specific QoL, aligning with existing literature indicating that the severity of HF, based on physical activity limitations and symptoms like dyspnea and angina, negatively impacts QoL (Singh et al., 2024). In elderly patients, a worse NYHA class was associated with impaired HRQoL, higher mortality and increased hospitalization rates (Luiso et al., 2022). Additionally, higher NYHA classes are also related to the presence of comorbidities, depression, and cognitive impairment in the elderly which further exacerbates the decline in QoL (Erceg et al., 2013). Furthermore, years with cardiac disease were significantly associated with overall health status suggesting that prolonged cardiac disease have negative impact on HRQoL. According to the literature the duration of cardiac disease does not show a clear direct correlation with HRQoL (Juenger, 2002). However a longer presence of cardiac disease is associated with increased number of comorbidities (Tran et al., 2022) and polypharmacy leading to complex treatment plans and difficulties in its management that is further related to increased hospitalizations, adverse drug reactions and decreased functional ability. All patients in the sample were prescribed with 12 or more medications, and mean number of 14 as co-existing diseases (SD = 3.3). Furthermore, the cumulative effect of cardiovascular risk factors like hypertension, obesity, and high cholesterol can lead to a progressive decline in HRQoL (Ba et al., 2002). The treatment also influences HRQoL outcomes; for instance, patients undergoing coronary artery bypass surgery, percutaneous transluminal coronary angioplasty and pacemaker implantation have been shown to significantly enhance HRQoL (Oliveira et al., 2008). According to our results, pacemaker significantly affected overall health status among elderly HF patients. Indeed, pacemakers can improve survival and manage symptoms in HF patients, and have been associated with significant improvements in QoL among elderly HF patients in physical, psychological, social, and environmental aspects (Comoretto et al., 2017; Hoth, 2008).

Furthermore, the results of the current study suggest a significant difference in frailty, indicating a lower overall health status among elderly HF patients. According to the literature, frailty is common among HF with HFpEF patients, which aligns with our sample characteristics with more than half of the sample (56.7%) having HFpEF. HFpEF is a syndrome that in its classical form is associated with multiple risk factors and comorbidities, which confer an extreme heterogeneity characterizing HFpEF. In addition to the clinical presentation, also the pathophysiological mechanisms are multiple. Altogether, these aspects largely account for the diagnostic challenges and the lack of a comprehensive treatment strategy in HFpEF patients (Gori et al., 2022). Frailty is related to increased vulnerability to adverse health outcomes, such as hospitalizations and mortality (Trivedi et al., 2022; Uchmanowicz & Gobbens, 2015). Moreover, frailty, even when not age-related, is often associated with mental health issues such as anxiety and depression, which also contribute to reduced HRQoL (Bart et al., 2023).

Regarding physical capability, measured by PROMIS, significant difference was found in all domains of HRQoL, which is in line with existing literature (Hägglund et al., 2008; Winter et al., 2023). Among elderly people with HF, physical limitations were associated with reduced activity and barriers to effective self-care (Holden & Mickelson, 2013) have negative impact on daily life activities that plays a significant role in the QoL of these patient (Hägglund et al., 2008). In addition, a significant difference with global QoL was found with a physical function, in particular lower body strength and endurance among elderly HF patients, which is also critical for maintaining independence in the elderly.

Another risk factor for poor self-care and higher dependence on others is cognitive decline - a prevalent issue in the aging population that is linked to reduced HRQoL (Munawar et al., 2023). The results of the study align with literature, indicating a significant difference in HRQoL based on cognitive status of elderly HF patients. Cognitive impairments can affect various aspects of daily living, including memory, problem-solving, and decision-making, which are crucial for maintaining independence and a high QoL (Doehner et al., 2023). Furthermore, the presence of cognitive impairment alongside frailty in HF patients increases the risk of adverse outcomes such as mortality and hospital readmissions, further diminishing HRQoL (Uchmanowicz et al., 2023).

Disease-specific QoL was found to be associated with anxiety and overall health status with depression. Anxiety may alter the subjective perception of HF severity, creating a disconnection between objective measures of disease severity and patients' personal assessments (Ponti et al., 2023). Furthermore, according to the results, overall health status was significantly different concerning patients’ illness perception. This is in line with the literature, as elderly patients who perceive their illness more negatively, which is influenced by their understanding and management of the illness, report poor QoL (Bobčíková & Bužgová, 2022). Depression often leads to functional impairments in the elderly, reducing their ability to perform daily tasks and maintain independence (Wróblewska et al., 2021). Furthermore, the presence of depressive symptoms exacerbates the challenges faced by elderly HF patients, leading to increased hospital readmissions and higher levels of symptom distress (Yeh & Shao, 2021).

HRQoL of elderly HF patients varies widely based on patient characteristics underscoring the need for holistic, person-centered and comprehensive approaches in assessing and improving their HRQoL.

4. UNDERSTANDING CARE MANAGERS' ROLE IN THE ESCAPE BCC

4.1. Aims and objectives

CM within the ESCAPE BCC framework has a great potential for providing chronic care and managing multimorbidity. However, in Italy, this role is not well-utilized. This study explored the perspectives of CMs on their role and functions within the ESCAPE BCC and the use of Meta-Algorithms for multimorbidity (MAM) (Muche-Borowski et al., 2017) at Bellaria Hospital in Bologna (IT) and Odense University Hospital in Odense (DK), utilizing a cross-sectional design with semi-structured interviews.

4.2. Participants and procedures

Recruited and trained by the ESCAPE CMs, who were performing care management tasks and implementing BCC intervention at Bellaria Hospital, Bologna (IT) and Odense University Hospital, Odense (DK) were invited to participate in the study. All participants were introduced to the current study and were asked to consent orally and in written form to be interviewed.

4.3. Assessments

Semi-structured interview was used to collect data regarding CMs' experience of performing care management functions in the implementation of individual care plans during the ESCAPE BCC intervention and use of MAM, designed by Muche-Borowski and colleagues (2017) to guide GPs through decision-making processes by considering the entire patient profile rather than focusing on isolated symptoms (Muche-Borowski et al., 2017). Qualitative data was collected in person at the Bellaria hospital for Italian CMs (N= 4) by GG and via MS

Teams online for Danish CMs (N= 2) by RS. Both interviewers (RS and GG) were PhD students in psychology at University of Bologna, Italy. Each CM was interviewed individually. Interviews lasted from 39 to 60 minutes and were audio recorded and transcribed verbatim with identifying data deleted. The individual interview approach was chosen to promote free expression and to avoid the influence of group dynamics or collective opinions on the topics under study.

The questions for interview guide were developed [**Appendix 3;Table 1**] after processing literature and discussion with the colleagues from University of Bologna (CR, SG) and the University of Southern Denmark (TT, SB). The questions development process was held in English. In Denmark, interviews to CMs were held in English, whereas in Italy questions were translated into Italian with a multiple back-forward translations approach. Supplementary questions were developed in advance and used as needed to assist in exploring the main topics.

CMs were familiar with BCC intervention, its structure and its main aims, since they had already been trained by the ESCAPE team to perform their role and functions. Therefore, during the data collection, participants were introduced only to the current study within the ESCAPE project, its method and purpose.

4.4. Data analysis

The theoretical thematic analysis was used to analyze data from semi-structured interviews to identify main themes regarding CMs perception on their role in BCC and MAM use as communication tool.

The analysis followed the six-step process that includes: familiarizing with collected data, initial codes generation, themes searching, reviewing, and defining themes, and producing report (Braun & Clarke, 2006; Kiger & Varpio, 2020). Transcripts were read multiple times and initial notes were made. Then each transcript was coded separately by each reviewer (RS and GG). As soon as each transcript was finished, it was coded and codes were compared, discussed and modified before moving further.

Data analyze followed open-coding, meaning developing and modifying codes during the analysis. Then codes were grouped into larger categories and preliminary themes had emerged. These themes were discussed until consensus was reached and final themes were achieved.

4.5. Results

4.5.1. Participants characteristics

Within the ESCAPE project, 5 nurses from Bologna, Italy, and 2 nurses from Denmark, Odense were locally recruited and trained to deliver the BCC intervention according to guidelines specifically designed by the ESCAPE team (Zelenak et al., 2023). At the time of the interview, all CMs had at least three months of experience delivering BCC. All five CMs in Italy and both in Denmark were invited to participate in the study. Only one CM in Italy declined to participate.

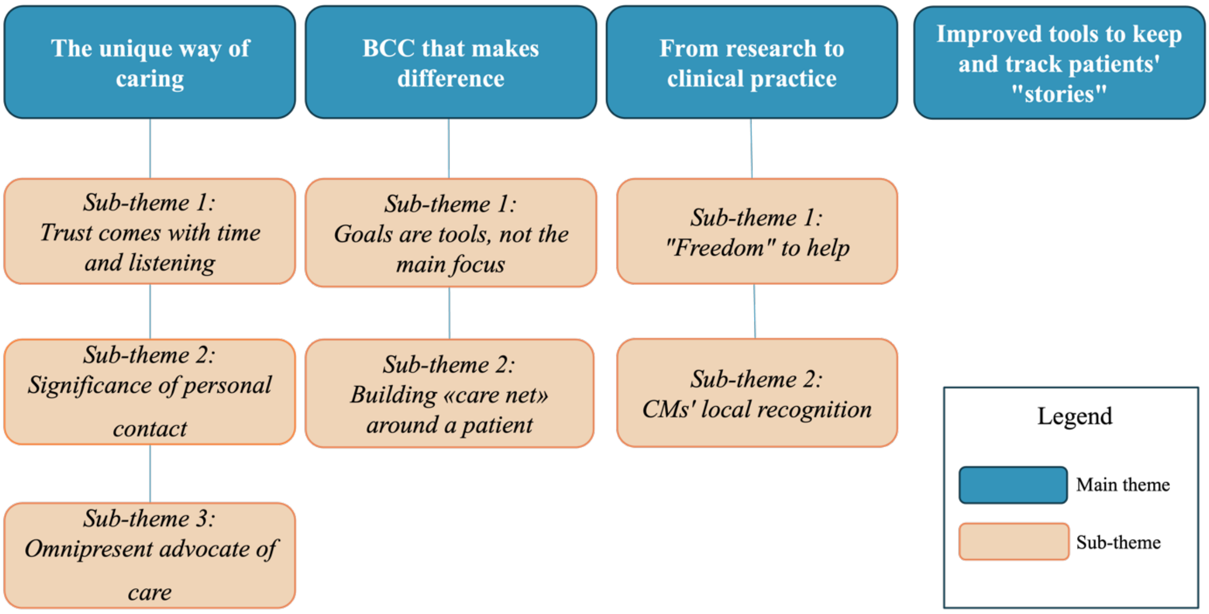
Among the Italian CMs, two nurses were from the Cardiology department of Bellaria Hospital, and two were family nurses part of IFeC initiative in Emilia Romagna region in Italy (D’Onofrio, 2022). Among the Danish CMs, one nurse was a project nurse at the Public Health department of the Southern Denmark University, and the other was a nurse at Odense University Hospital.

4.5.2. Themes from thematic analysis

The qualitative analysis revealed 4 main themes “The unique way of caring”, “BCC that makes difference”, “From research to clinical practice” and “Improved tools to keep and track patients’ stories” [**Figure 2**]. These themes shed light on the CM's views regarding their role within BCC and in assisting patients with their complex treatment plans. Further, it highlighted the necessary adaptations within BCC to meet local healthcare requirements, as well as the significance of local acknowledgment of the CM's role in delivering care anchored in trust-based relationships with patients, emphasizing dedicated time per patient and continuous availability to address their needs.

Figure 2

Thematic analysis results



The unique way of caring theme describes the relationship CMs build with patients to deliver proactive care and facilitate patients' health behavior change. The theme is divided into 3 sub-themes: "Trust Comes with Time and Listening", "Significance of personal contact" and " Omnipresent advocate of care". The first sub-theme "Trust Comes with Time and Listening" highlights the importance of adaptation, availability, and personalized support, emphasizing the role of listening and empathic communication in fostering deep connections between CM and patient.

> *"… For some people, the fact of feeling like this… feeling that there is a person who anyway periodically listens to them, sometimes the phone calls are just chats."* (CM3)

CMs adjusting their interventions to meet the unique needs of each patient, ensuring that their support is both relevant and effective. At the heart of this sub- theme is the recognition that trust is not instantaneous; it develops gradually through consistent, empathic interactions. CMs shared that, in order to truly support their patients, they must go beyond addressing treatment-related issues.

> *"Of what she feels, how she is, what she would like to do, what she can no longer do, what she did when she was young, about her children… yeah, I gave a bit more space to this, and I think that's why a close bond was created. A more trusting one…"* (CM4)

CMs facilitate an environment where patients feel understood and supported, free to share their fears and intimate concerns without fear of judgment. This open, compassionate approach enables patients to feel valued and heard, laying the groundwork for a trustful relationship. CMs prioritize listening as a core strategy to build trust, spending time understanding their patients' health situations, preferences, and values. They recognize that listening is not just about hearing; it is about truly understanding and empathizing with the patient's experience.

> *"I think that the patient has been, if I measure the relationship in how open the patients has been and how they have been telling me all kinds of things, thoughts of death, worries about life, worries about or wishes for being intimate with their partners or having a sexual partner. It came as, it was in number one or two conversation."* (CM6)

Dedicating sufficient time to understand patients' needs and concerns, CMs create an environment where patients feel valued and heard, which is essential for effective patient-centered care.

> *"But of course, if the patient tells me that she would prefer that there was time to listen … I think most of the patients I've met - that's the issue: the time. The time is not there in this healthcare system. And they feel like they're just being brushed out the door all*

> *the time, and they are not being taken seriously, and they are feeling like a burden on the doctors ...”* (CM7)

The second sub-theme, "Significance of Personal Contact," highlights the critical role of face-to-face interactions in the work of CMs and their relationships with patients and caregivers. This theme underscores the limitations of care delivered solely via phone and the challenges it presents in assessing the patient's context remotely. BCC is specifically designed to be phone-based (Zelenak et al., 2023) and therefore, CMs' perceived lack of personal contact highlights the importance of appropriately adopting BCC to local healthcare settings as well as care provider needs.

> *“And you know, if you could actually… if you could take the baseline interview in person and then keep on, then you can continue by phone. That would be super-efficient, if you ask me, because the relationships are hard to establish on the phone with some of the patients”* (CM7)

According to CMs it difficult to rely solely on phone communication, as it can feel incomplete and make it harder to keep track of the patient's progress. The absence of personal contact is a significant challenge, as CMs must trust the patient's words about their health without the ability to observe their condition directly. This reliance on verbal descriptions can lead to a sense of missing out important nuances that are visible only through personal interaction.

> *“… fact of not being able to see the person, not being able to see the context in which they live, not being able to see certain things, makes it difficult to understand ...what they tell you is realistic…”* (CM3)

Personal contact is also essential for establishing a trustful relationship, as it allows CMs to see the real progress of the patient and adapt their interventions accordingly. This direct observation helps in shaping the broader care context.

> *"Yeah, I think it's very-very important for the building of trust. And that is actually the thing with that I miss where I miss the personal contact the most is in the beginning and in the upstart, the baseline phase."* (CM7)

The third sub-theme "Omnipresent Advocate of Care" highlights the pivotal role of CMs as constant and reliable advocates for their patients. This theme underscores the importance of CMs as a reference figure for any inquiry, helping patients navigate the complex healthcare system and facilitating communication with their GPs. Ivynian and colleagues (2020) emphasized that patients often rely heavily on healthcare providers for information and support regarding HF. However, many patients reported unmet educational needs, particularly concerning the quality of communication. Barriers to effective patient-provider communication identified in their study included the use of complex medical terminology, insufficiently detailed information, relationships that did not encourage open dialogue, and patients' memory challenges (Ivynian et al., 2020). CMs perceived themselves as needing to be consistently available, providing a reliable presence that patients can depend on. This availability, combined with a patient-centered approach, helps to improve the relationship over time, transforming it from a purely professional interaction into a more personal and trust-based connection.

> *"It's an important relationship. However, it seems much stronger than with the physician. The physician goes there, prescribes the therapy, gives some advice, but in the end, you are [CM figure] his reference point instead. So, it seems to me a rather important and engaging relationship. And for the patient having someone, a reference point who listens to you and can help you solve certain needs, I would say that… is quite important."* (CM2)

CMs serve as a consistent point of contact for patients, providing a sense of stability and reliability that can be lacking in interactions with other healthcare professionals. Unlike nurses, who may vary from visit to visit, CMs are always the same person to contact, ensuring continuity and familiarity in the patient's care journey. By acting as a liaison, CMs ensure that patients' needs and concerns are clearly conveyed and addressed.

> *"You have to make them understand what your role is, what the appropriate path for their health is, but you have to make them realize it in a way that they come to that understanding on their own"* (CM1)

Such advocacy extends beyond mere information exchange; it involves helping patients understand the broader context of their health and the various components of their care plan.

"BCC that makes difference" theme focuses on what among BCC elements makes it special and different from CMs usual role as nurse in care for elderly HF patients. The theme is divided into 2 sub-themes as follows: "Goals as Tools, Not the Main Focus" and "Building a Care Network Around the Patient". The first sub-theme "Goals as Tools, Not the Main Focus" highlights the specific approach to goals in the context of BCC for elderly HF patients. Within the ESCAPE BCC, goals are set collaboratively with GPs and patients' preferences and represent a focus of the CMs contacts. CMs responsible not only in setting appropriate achievable goals but also for monitoring them and facilitating patients' behavior related change to achieve them. The key insight of this sub-theme is that while goals are important, they are viewed by CMs as tools to facilitate care rather than the primary objective. This perspective emphasizes the importance of setting smaller, step-by-step goals that aligned with the patient's needs and preferences.

> *"Actually, this SMART goal method that we've learned, I mean, that we use in the ESCAPE, I've implemented it with patients, and I believe it works, it works."* (CM1)

Such an approach helps to maintain motivation and momentum, making the goals more attainable and less overwhelming for the patient. Patients are often suggested with recommendations from medical specialists regarding their health improvement, for instance weight loss or healthy diet, which is usually quite challenging for the patient. This could be due to complex health picture or lack of motivation and support. Therefore, according to CMs, their role addresses a critical gap in healthcare - providing support and assistance to patients beyond the traditional "doctor's office" setting. This extended support aims to improve patients' daily lives, which in turn has the potential to enhance their overall health-related situation. The process of working towards goals is valued by CMs as much as the achievement itself.

> *"So, this system that we… if we have a care manager function ["in our healthcare system"], it has to be flexible at all points. You have to be able to change the preferences and the goals and you have to change that and be able to do so all the time because it changes with their ["patient's"] condition and if they are a period where, if they are sad for something, if something happens to them and they get depressed and everything just stops and then it's a whole lot of preference and a whole lot of need and some other goals you have to attend to at that point."* (CM7)

According to CMs, goals are flexible and can be adjusted based on the patient's preferences and progress, allowing the care plan to evolve in response to the patient's changing needs and circumstances. In this way, it is not the patient who has to adapt to treatment, but treatment that builds up around the patient meeting his/her needs.

> *"And you can't really push them ["patients"]. You can't really, because then you are an added stress and some of my patients when I have been talking goals I kind of always try to adjust it and maybe we can just take it a little baby step. You ["as CM"] try to kind of nudge without pushing too hard because you know that, and you can just hear in the voices that it's too much."* (CM7)

CM shared that the focus should be towards one goal at a time, which helps to avoid overwhelming the patient. Initial preferences often include activities from the past that the patient enjoyed or found meaningful but cannot engage due to his/her health condition.

> *"And what has happened since that we spoke in these stories they tell us or they talk about the symptoms and they talk about situations, and they talk about what they are bothered by, and what they wish to do, and what they wish they could do, and I grabbed to these things and asked them about if this is a goal for next time or is this is a goal."* (CM6)

The second sub-theme "Building a Care Network Around the Patient" highlights the importance of establishing a network around the patient, emphasizing the critical role of specialist team support in guidance for CMs, particularly for complex cases and challenging patient scenarios. Specialist Team in the ESCAPE BCC is a team that holds regular meetings for patients' updates in BCC and care coordination and consists of, but it is not limited to, cardiologist, pharmacologist, psychologist or psychotherapist (Zelenak et al., 2023). This support is not just beneficial for CMs but necessary, especially when dealing with complex cases that require specialized knowledge and skills. The specialist team helps CMs navigate difficult situations, providing the guidance and assistance needed to address the patient's needs effectively.

> *"Having various professionals all together listening to what you say, and each giving their opinion, it actually is really helpful."* (CM1)

The specialist team's ability to take cases seriously and provide timely support is a key factor in the success of the BCC care. Team discussions are highlighted by CMs as more effective than individual consultations with each specialist separately.

> *"I mean I don't... I don't feel like doing something which makes me say "Ok, I'm just talking about thin air", you know? Like when you sometimes ask for an opinion or something individually from... other figures."* (CM1)

This collaborative approach allows for a more comprehensive and coordinated response to patient needs, ensuring that all aspects of the patient's care are addressed.

From research to clinical practice theme. The theme included two sub-themes: "Freedom to Help" and "CMs' Local Recognition and Integration". The first sub-theme "Freedom to Help" highlights the importance of providing CMs with the freedom and flexibility to adapt their tasks within the BCC framework. CMs follow a specific guideline developed by the ESCAPE team that describes each step of CMs work with patients and specify procedure for difficult cases or adverse events. Consequently, the CMs role is highly structured, thus it does not always enable them to actively assist patients. CMs expressed a desire for a greater involvement in problem-solving and the ability to engage with patients at every stage of their disease trajectory.

> *"So that I have found it sometimes difficult, and I have tended between supporting the patient to find goals or supported the patient in their thoughts or in their behavior or trying to change the behavior. But at the same time, pending in my usual nurse role, which is problem solving. So, this time I shouldn't always solve the problem, but I should support the patient in solving the problem. And that has been sometimes difficult and frustrating"* (CM6)

CMs appreciate the structured approach of BCC, which provides a clear framework for care. However, they also value the freedom to adapt their tasks to meet the various unique needs of each patient. Kennedy and colleagues (2017) found that HF patients and caregivers seek education on disease specifics, quality of life improvement, and coping strategies for future care decisions (Kennedy et al., 2017). Similarly, the PPI phase of the ESCAPE project identified key patient preferences, including education on HF and comorbidities, patient involvement in care, improved communication with healthcare professionals, symptom monitoring, and regular updates on disease progression (Gostoli, Bernardini, et al., 2024). Access to medical files allows CMs to be more active and engaged in the care process, enabling them to provide personalized support.

> *"If the care manager was in a position that you could see, for example, the medical journals and the medicine lists and the information of admissions to the hospital and doctors' visits and all this stuff, then you would have... then you would be able to insert yourself more in their care and take a more coordinating role and like..."* (CM7)

Also, CMs would like to be more active and problem-solving in their case of the patient. While CMs are skilled in communication techniques, there is a recognition that they should also be more active in addressing and solving patient problems. This requires a balance between the structured nature of BCC and the need for flexibility and independence in CM roles.

> *"But I think that would be very efficient if the care manager role existed on these premises where you could kind of take a more active and you can insert yourself more in the... in the problem solving and the actual contact."* (CM7)

CMs should be able to meet patients at every level of their disease, which necessitates a broad skill set and the ability to adapt to different situations. This requires a certain level of freedom within the BCC structure. Additionally, care navigation for patients requires more time within BCC, as CMs are constantly seeking approval from GPs or other responsible medical personnel. This can be challenging, given that these professionals are often difficult to reach due to their lack of time.

> *"I can see the validity of it, but it has to be really flexible in order to work with these kinds of patients. And that, I think, is kind of the big picture of this whole project. It has*

> *to be flexible, it has to be adjustable, it has to be the care manager function has to be a size that can be altered according to the patients and not the other way around because some patients you can't discuss goals and it's just about getting them to hang on basically and you have to be able to meet the patient on every level of their disease and their existence and their problems and their thoughts."* (CM7)

The second sub-theme "CMs' Local Recognition and Integration" highlights the critical importance of local recognition and integration of CMs within the healthcare system. It extends the challenges faced by CMs in collaborating with GPs and other medical personnel, and the need for CMs to be recognized as separate and valuable figures in patient care. This recognition is essential for their ability to coordinate and collaborate with other healthcare professionals.

> *"If you require a Care Manager to do this type of activity with patients, there must be the possibility to dedicate specific time, which is then recognized, or to have additional personnel dedicated to being a Care Manager…"* (CM3)

Further, CMs acknowledge the importance of collaboration with GPs to assist with patient care, as the GP is responsible for patient's treatment. The lack of official acknowledgment of the CM figure in local healthcare makes it challenging for them to truly perform their coordinator role and refer patients to appropriate assistance. GPs are often overloaded with daily tasks and have limited time per patient, making it difficult for CMs to rely on them for everything.

> *"The GP has to refer to different kind of offers that exist for the patients. And so, because we have to work together and rely on the GPs, our position is challenged by this."* (CM7)

The theme also touches on the adaptation of BCC and its tools, such as MAM and imergo® to better suit the needs of CMs in clinical practice. Due to the ESCAPE BCC project being developed with a research focus, many tasks performed by CMs were related to research purposes, making it challenging for CMs to integrate these tasks into clinical practice. Local adaptation and the transfer of the CM role and BCC from research to clinical practice are expected to improve care delivery.

The theme "Improved tools to keep and track patients' stories" highlights the need for tools that effectively maintain and monitor patients' stories within the BCC framework, which is also adapted locally. The current tools, such as MAM and imergo®, face limitations that hinder their effectiveness. MAM, while it is useful for GPs to communicate treatment plans and build goals, is not well-suited for evaluating psychiatric distress and is time-consuming to arrange and share according to CMs.

> *"Is there a reason why he said it there and not here [in MAM]? Or if the preferences written there are very different from what they tell you, then let's say it gives you guidance on how to establish a relationship with the patient to reach the goal that he, anyway mentioned, so… you can't ignore that."* (CM1)

Furthermore, imergo®, a software designed by the ESCAPE for CMs, is reported by CMs to be too complex, making it challenging for them to use effectively. The software's design, which requires placing patient stories into predefined categories, proves difficult and does not allow CMs to give their full attention to patients during calls. This complexity hinders the CMs' ability to provide personalized and attentive care, as they are preoccupied with navigating the intricacies of the software.

> *"But sometimes the information that patients give you is very hybrid, very mixed. So it also becomes complex to try to categorize them under a specific theme or in a specific place".* (CM3)

Additionally, imergo® is time-consuming for record-keeping and prone to generating redundant or irrelevant recordings for BCC delivery, further complicating its use. These challenges underscore the need for more efficient, user-friendly, and adaptable tools that can better support CMs in their work. Such tools would ultimately improve patient outcomes, and the quality of the care provided.

> *"There are things that in my opinion are fundamentally not so relevant. I mean, yes, I'm interested in knowing that the patient has control X and control Y, but I don't see the need to always report it every time when it needs to be done or if it has already been done" (CM3)*

4.6. Discussion

The exploration of CMs' perspectives on their role and functions in BCC and MAM use revealed that building trust with patients through active listening and dedication of sufficient time is highly important to understand patients' needs. This creates an environment where patients feel comfortable sharing their fears and worries, allowing CMs to deeply understand the patient's concerns and address them in a non-directive, proactive manner. This approach is markedly different from what patients typically receive in usual care provided by nurses, which may not prioritize the same level of individualized attention or emotional engagement. Similarly to CMs, family nurses, widely used in chronic care, involve supervising situations, providing guidance, creating partnerships, and a management style that is both dynamic and static, with antecedents like chronic health status and socioeconomic factors influencing its conductance (Sun et al., 2022). However, CMs, also in the ESCAPE BCC project, provide a consistency in case delivery along with support and patient motivation, focusing on the individual needs of patients and working directly with them to assess their specific health requirements, develop personalized care plans, and monitor their progress. They play a critical role in linking patients to necessary resources, advocating for their needs, and ensuring that care is delivered efficiently and effectively. Indeed, according to CMs, the ESCAPE BCC elements, such as motivational goal-oriented communication based on needs, specialist team supervision and extensive network involvement, make it beneficial for patient care.

CMs collaborative goal setting process allows the establishing of realistic and achievable objectives for patients care, which are carefully aligned with the patient's health priorities and values, ensuring that the care plan is personalized and meaningful. As a result, patients feel more engaged and empowered in their health management. Moreover, the goals serve as a roadmap for care, guiding the management of the patient's condition and the provision of support services. CMs do not view goals as focus of care but rather as integral components that help structure and direct the overall care journey. Additionally, collaborative goal setting within BCC strengthens the therapeutic relationship between patients and CMs, and it does refer not only to clinical care, but it also involves the understanding of patient's psychological and emotional needs. This is particularly important for elderly frail patients who may feel powerless, undermining their self-care and commitment to treatment (Neeman, 1995). Eckerblad and colleagues (2023) noted that older patients often link self-care to basic hygiene practices, physical activity, medication adherence, maintaining a healthy diet, and ensuring adequate rest. However, self-care for these patients also extends to engaging in hobbies, preserving independence, participating in social activities, and fostering a supportive environment (Eckerblad et al., 2023).

Regarding BCC elements, the specialist team introduced by the ESCAPE BCC project not only coordinates care to ensure it is evidence-based but also provides essential support to CMs, especially in managing complex or difficult cases. These team meetings are highly valuable to CMs, as they offer a platform where they feel heard and supported. According to

CMs, this collaborative environment is significantly more effective than individual meetings with each specialist. Having an extensive support network is crucial for CMs in BCC, as their primary role is to coordinate care rather than actively solve problems. Moreover, according to CMs, the involvement of caregivers in the care network is particularly beneficial. Caregivers not only help motivate patients but also serve as an additional source of information and assistance. Their inclusion strengthens the care network, making it more responsive and comprehensive. By leveraging the expertise and insights of both specialists and caregivers, the BCC approach ensures that patients receive the highest quality of care.

Further CM recognition is essential for such a figure to exist in the future of healthcare and be able to provide and navigate patients in such a wide care net. It is challenging to refer patients to services that are not familiar with the CM role. Additionally, CM recognition should come with dedicated time and resources. As CMs spend a lot of time in communication with patients as part of their support and trust-building, it cannot be a part of someone else's job, such as a nurse's, even though it shared some similarities in tasks and functions.

In addition, CMs within the framework of the ESCAPE BCC project provide a consistent and structured care approach based on manuals. This structured approach often limits their ability to actively assist patients in the dynamic and hands-on manner that nurses typically do. Consequently, CMs would greatly benefit from enhanced flexibility and the capacity to actively solve problems, allowing them to provide more responsive and personalized care to meet the diverse needs of patients. Moreover, the availability and willingness of GPs to assist CMs in care coordination can be a significant factor. In BCC, CMs strictly follow GPs' recommendations and regularly update them on patients' progress. Therefore, CMs rely on GPs’ feedback for effective BCC delivery and coordination. Nonetheless in some cases, CMs reported GPs’ lack of time and motivation to provide adequate support to them. This can result in insufficient support to the patient, delays in addressing patients' issues, or difficulties in patient coordination.

Regarding the tools specifically designed by the ESCAPE project for BCC management, CMs recognize the potential of MAM and imergo® software in improving patient care. However, they emphasize the need for these tools to be adapted to better suit clinical practice, since they were originally designed for research and are not fully optimized for the dynamic environment of clinical settings. CMs perceive that while MAM is effective for documenting static patient details, it falls short in capturing the fluctuating aspects of patient conditions, such as psychological states, which are critical in BCC. Furthermore, CMs perceive that MAM effectiveness is contingent upon GP motivation, which is often hindered by time constraints, and it requires improvement for CMs use. Similarly, imergo®, despite its comprehensive data-tracking capabilities, is overly complex and not well-aligned with the specific needs of BCC and MAM in clinical practice. The software interface, structured around blocks and boxes, is not conducive to capturing the nuanced and fluid nature of patient narratives, making it difficult for CMs to use, especially during calls when quick access and updates are necessary.

Both the local recognition of CM and its adaptation to the local setting would be beneficial for the work of CMs, enabling them to address patient needs more effectively and efficiently, as well as optimize the use of BCC specific tools. In summary, the perspectives of CMs on their roles in BCC and MAM reveal a multifaceted approach to patient care that prioritizes trust, communication, and collaboration. By recognizing the unique contributions of CMs and addressing the systemic challenges they face, healthcare systems can better leverage their expertise to improve patient care and outcomes in cardiac health.

5. CONCLUSION

HRQoL provides a comprehensive understanding of patients' health-related status and encompasses various dimensions, including physical, mental, and social well-being (Johansson et al., 2022). Therefore it plays an important role as one of the principal outcomes in the development and efficacy of person-centered holistic care plans, such as the ESCAPE BCC (Zelenak et al., 2023), that are designed not only to address the clinical aspects of a patient's condition but also to consider the broader implications for their daily life (Knudsen et al., 2024).

The results of the current study showed that HRQoL is associated with factors, such as NYHA class, duration of cardiac disease, number of co-existing disorders, number of prescribed medications, implanted pacemaker, perceived physical capability, physical function, frailty, cognitive impairment, illness perception and psychological distress, that were already known and well described in the literature. Among them, the fact that the duration of years with cardiac disease and cognitive impairment were directly associated with HRQoL in the sample, represents a novel aspect as both factors do not broadly affect HRQoL according to literature, but were found to be related to disease severity, disease progression, self-care and self-efficacy among elderly HF patients with multimorbidity. The findings add an important piece to better understand the complexity of the clinical, psychological and social structure of these patients and emphasize the need for a comprehensive and integrated approach to care for elderly HF patients with multimorbidity. As proposed by the ESCAPE project, the BCC approach, delivered by a dedicated figure, such as CM, may offer a promising avenue for addressing such complexity of this patient population.

The findings of this study, which are included in the present thesis, have relevant implications that extend beyond merely enhancing the classification of elderly HF patients with multimorbidity. They also highlight the potential benefits of incorporating CM into clinical practice, especially in Italy where this role has received limited attention both in research and practice. In Italy, the concept of CM is relatively novel and there have been few studies or initiatives focused on this role. However, if the ESCAPE project succeeds in achieving its goals, the insights and reflections provided by the CMs who participated in the project could be invaluable. These insights could help in defining and establishing the role of CMs within the Italian National Health Service (NHS).

The CMs, recruited by the ESCAPE project, have shared their experiences and thoughts on how they can contribute to patient care. Their reflections could serve as a foundation for building a comprehensive framework for the CM role in the NHS. This framework could include the specific responsibilities of CMs, the training they need, and how they can work effectively within healthcare teams to improve patient outcomes.

By leveraging the experiences and reflections of the CMs from the ESCAPE project, Italy could develop a more structured and evidence-based approach to integrating CMs into its healthcare system. This would not only enhance the quality of care for patients but also provide a clearer career path and professional identity for individuals aspiring to become CMs in Italy. Indeed, the BCC approach facilitated by CMs, offers a promising strategy for addressing the multifaceted needs of elderly HF patients with multimorbidity by focusing on enhancing patients' self-efficacy and providing tailored care that considers both physical and psychological well-being. However, the ESCAPE BCC requires adaptation to meet the needs of clinical practice, as it is currently designed for research purposes and is overly complex for the CMs to follow.

5.1. Limitations of the studies

Limitations of this study include a relatively small sample size that cannot be considered representative of all elderly multimorbid patients with HF. The present study is in a frame of the ESCAPE BCC (Zelenak et al., 2023) and was limited by its timeframes and regulations.

The significance of the Fisher exact test and U Mann-Whitney test results also could have been influenced by the small sample size. In addition, due to the small sample size, observed associations may be affected by sampling bias. Only complete data were considered for the analysis to ensure data consistency and validity. The presence of missing data was not expected to bias the results. Moreover, due to the nature of the present study, a power analysis was not executed. However, this study is preliminary and exploratory in nature, and it does not intend to establish definitive correlations. Furthermore, among the limitations of the qualitative study within the research, subjectivity, limited generalizability and potential over-simplification should be considered. In addition, CM in Italy and in Denmark were interviewed with differences in settings. In Italy interview were performed in person and in Italian language, whereas CM from Denmark were interviewed via video call in English that is not their native language.

5.2. Ethical considerations

The study 1 was based on data from the Italian sample of the European project entitled "Evaluation of a patient-centred biopsychosocial blended collaborative care pathway for the treatment of multi-morbid elderly patients" (ESCAPE; Grant agreement No 945377) that was approved by Comitato Etico di Area Vasta Emilia Centro (CE-AVEC) at Sant'Orsola-Malpighi Polyclinic, University of Bologna ("Azienda Ospedaliero-Universitaria di Bologna, Policlinico S. Orsola-Malpighi", Protocol N. PG0012699/2021). All participants were fully informed about the study, the voluntary nature of their participation, confidentiality and anonymity, and they all gave their written consent to participate in this study.

The study 2 involving care managers (CMs) recruited by the ESCAPE Project (Grant agreement No 945377) was approved by Etico Area Vasta Emilia Centro (CE-AVEC) at the department of psychology "Renzo Canestrari", Università di Bologna (CE 518-2023-OSS-AUSLBO). All participants were fully informed about the study, the voluntary nature of their participation, confidentiality and anonymity, and they all gave their oral and written consent to participate in this study.

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APPENDIX 1

Table 1
Baseline Assessment Battery.

Outcome	Measurement tool
Clinical data (*e.g., NYHA class, systolic function, years with cardiac disease, co-existing disease, symptoms and prescribed medications, cardiac interventions*)	Self-report, verified by hospital discharge notes, electronic medical records (if available) and information obtained from treating physicians and informal caregiver.
Adherence, physical and cognitive status	
Medical treatment adherence	Medication Adherence Report Scale (MARS-5) a 5-item instrument to elicit patients' reports of non-adherence with medical treatment recommendations.
Physical function / capability	30 second chair stand test (30s-CST) to measure physical function, supplemented by the 4-item self-reported PROMIS Physical Function Short Form 4a (physical capability).
Physical activity	4-item International Physical Activity Questionnaire for the elderly (IPAQ-E).
Cognitive impairment	Montreal Cognitive Assessment (MoCA) - the 15-item questionnaire to screen for cognitive impairment, supplemented with 2 custom questions regarding memory decline.
Frailty	Self-report for frailty components, where participants are classified into non-frail, pre-frail, and frail individuals which was conceptually designed after the established Fried Frailty Phenotype.
Illness perception, loneliness and resources	
Illness perception	9 items of the Illness Perception Questionnaire (IPQ-Brief) to assess cognitive representation of medical condition.
Patient Acceptable Symptom State	2 questions based on Patient Acceptable Symptom State (PASS).
Perceived emotional social support	ENRICHD Social Support Inventory (ESSI) developed in the ENRICHD trial.
Meaning and spirituality	12-item FACIT Sp-12 scale
Loneliness	3-item version of the UCLA Loneliness Scale.
Health literacy	Patients' confidence in their ability to understand personal medical information will be measured with the four-item BRIEF Health Literacy Screening.

Psychological variables	
Psychological distress	Hospital Anxiety and Depression Scale (HADS; 14 items) was used to measure severity of anxiety and depressive symptoms in physically ill patients. It is a self- rating instrument on a four-step Likert-Scale with 14 items.
Anxiety	Sub-scale HADs for anxiety
Depression	Sub-scale HADs for depression
Depressive symptoms	PHQ-4
Perceived stress	4-item Perceived Stress Scale (PSS-4) will be used to measure measuring subjectively perceived distress.
Treatment burden	10-item version of the Multimorbidity Treatment Burden Questionnaire (MTBQ)
Quality of life	
Global quality of life and subjective overall health status	The EQ-5D-5L with a visual analogue scale (EQ-VAS) to measure the global subjective health status (0 - 100).
Disease specific quality of life	Kansas City Cardiomyopathy Questionnaire (KCCQ-12) with 12 items to assess quality of life specifically related to living with HF.

APPENDIX 2

Table 1

Health related QoL and clinical data (N=33)

Clinical data	Global QoL			Overall health status			Disease specific QoL				
	Positive N (%)	Negative N (%)	*p* value	Low N (%)	High N (%)	*p* value	Good to excellent N (%)	Fair to good N (%)	Poor to fair N (%)	Very poor N (%)	*p* value
NYHA[1]			.221			.182					.020
I -II	10 (76.9)	5 (50.0)		3 (42.9)	12 (75.0)		3 (100)	10 (83.3)	2 (28.6)	0 (0)	
III-IV	3 (23.1)	5 (50.0)		4 (57.1)	4 (25.0)		0 (0)	2 (16.7)	5 (71.4)	1 (100)	
EF[2]			.379			.322					.935
< 40%	4 (26.7)	2 (13.3)		3 (25.0)	3 (16.7)		0 (0)	4(28.6)	2 (18.2)	0 (0)	
41-49	2 (13.3)	5 (33.3)		1 (8.3)	6 (33.3)		1 (33.3)	3 (21.4)	2 (18.2)	1 (50.0)	
≥50%	9 (60.0)	8 (53.3)		8 (66.7)	9 (50.0)		2 (66.7)	7 (50.0)	7 63.6)	1 (50.0)	
Years with cardiac disease[3]			.689			.035*					.601
>5	4 (26.7)	5 (38.5)		6 (60.0)	3 (16.7)		0 (0)	5 (35.7)	4 (44.4)	0 (0.)	
≤5	11 (73.3)	8 (61.5)		4 (40.0)	15 (83.3)		3 (100)	9 (64.3)	5 (55.6)	2 (100)	
Number of co-existing diseases			.166			.148					.102
≤14	12 (70.6)	7 (43.8)		5 (38.5)	14 (70.0)		3 (75.0)	11 (73.3)	3 (27.3)	2 (66.7)	
>14	5 (29.4)	9 (56.3)		8 (61.5)	6 (30.0)		1 (25.0)	4 (26.7)	8 (72.7)	1 (33.3)	
Number of prescribed medications[2]			.466			1.000					.216
< 5	0(0)	0 (0)		0 (0)	0(0)		0(0)	0(0)	0(0)	0(0)	
5 - 11	9 (60.0)	6 (40.0)		6 (50.0)	9 (50.0)		3 (100)	7 (50.0)	5 (45.5)	0 (0)	
≥12	6 (40.0)	9 (60.0)		6 (50.0)	9 (50.0)		0 (0)	7 (50.0)	6 (54.5)	2 (100.)	
Coronography[4]			1.000			1.000					.105
Yes	8 (53.3)	7 (50.0)		6 (50.0)	9 (52.9)		0 (0)	10 (71.4)	4 (40.0)	1(50.0)	
No	7 (46.7)	7 (50.0)		6 (50.0)	8 (47.1)		3 (100)	4 (28.6)	6 (60.0)	1 (50.0)	
Bypass surgery[4]			1.000			1.000					1.000
Yes	1 (6.7)	1 (7.1)		1 (8.3)	1 (5.9)		0 (0)	1(7.1)	1 (10.0)	0 (0)	
No	14 (93.3)	13 (92.9)		11 (91.7)	16 (94.1)		3 (100)	13 (92.9)	9 (90.0)	2 (100)	
Heart valve treatment[4]			.215			1.000					.690

Yes	2 (13.3)	5 (35.7)		3 (25.0)	4 (23.5)		0 (0)	5(35.7)	2 (20.0)	0 (0)	
No	13 (86.7)	9 (64.3)		9 (75.0)	13 (76.5)		3 (100)	9 (64.3)	8 (80.0)	2 (100)	
Pacemaker[4]			.598			.246					1.000
Yes	1 (6.7)	2 (14.3)		0 (0)	3 (17.6)		0 (0)	2 (14.3)	1 (10.0)	0 (0)	
No	14 (93.3)	12 (85.7)		12 (100)	14 (82.4)		3 (100)	12 (85.7)	9 (90.0)	2 (100)	
Defibrillator[5]			1.000			.499					1.000
Yes	1 (7.1)	1 (7.7)		0 (0)	2 (12.5)		0 (0)	1(7.1)	1 (11.1)	0 (0)	
No	13 (92.9)	12 (92.3)		11 (100)	14 (87.5)		2 (100)	13 (92.9)	8 (88.9)	2 (100)	

Note: NYHA - New York Heart Association Functional Classification; EF – ejection fraction; 1-These data were calculated on sample of N=23 due to missing data; 2-These data were calculated on sample of N=30 due to missing data; 3-These data were calculated on sample of N=28 due to missing data; 4-These data were calculated on sample of N=29 due to missing data; 5-These data were calculated on sample of N=27 due to missing data. *p value < .05

Table 2

Health related QoL and medical adherence, physical and cognitive status (N=33)

Clinical data	**Global QoL**			**Overall health status**			**Disease specific QoL**				
	Positive N (%)	**Negative N (%)**	***p* value**	**Low N (%)**	**High N (%)**	***p* value**	**Good to excellent N (%)**	**Fair to good N (%)**	**Poor to fair N (%)**	**Very poor N (%)**	***p* value**
Medical adherence			.728			1.000					.755
Highly adherent	8 (47.1)	6 (37.5)		6 (46.2)	8 (40.0)		1 (25.0)	8(53.3)	4(36.4)	1(33.3)	
Partly adherent	9 (52.9)	10 (62.5)		7 (53.8)	12 (60.0)		3 (75.0)	7 (46.7)	7 (63.6)	2 (66.7)	
Physical function[1]			.033*			.275					1.000
Normal	11 (100)	1 (33.3)		1 (50.0)	11 (91.7)		3 (100)	8 (80.0)	1 (100)	0	
Not normal	0 (0)	2 (66.7)		1(50.0)	1 (8.3)		0 (0)	2 (20.0)	0	0	
Physical capability			.002*			.022*					< .001**
Worse than average	7 (41.2)	15 (93.8)		12 (92.3)	10 (50.0)		0 (0)	8 (53.3)	11 (100)	3 (100)	
Better than average	10 (58.8)	1 (6.3)		1 (7.7)	10 (50.0)		4 (100)	7 (46.7)	0 (0)	0 (0)	
Physical activity[2]			.078			.064					.054
High	5 (31.3)	1 (6.3)		0 (0.)	6 (30.0)		2 (50.0)	4 (28.6)	0 (0)	0 (0)	
Low	4 (25.0)	10 (62.5)		8 (66.7)	6 (30.0)		0 (0)	4 (28.6)	8 (72.7)	2 (66.7)	
Moderate	7 (43.8)	5 (31.3)		4 (33.3)	8 (40.0)		2 (50.0)	6 (42.9)	3 (27.3)	1 (33.3)	
Frailty[2]			.265			.050*					.052
Frail	10 (58.8)	12 (80.0)		11 (91.7)	11 (55.0)		1 (25.0)	8 (57.1)	10 (90.9)	3 (100)	
Pre-frail	7 (41.2)	3 (20.0)		1 (8.3)	9 (45.0)		3 (75.0)	6 (42.9)	1 (9.1)	0 (0)	
Cognitive impairment[2]			.042*			.118					.163
Severe	2 (11.8)	1 (6.7)		1 (8.3)	2 (10.0)		1 (25.0)	1 (6.7)	1 (9.1)	0 (0)	
Moderate	4 (23.5)	10 (66.7)		8 (66.7)	6 (30.0)		1 (25.0)	4 (26.7)	7 (63.6)	2 (100)	
Mild	11 (64.7)	4 (26.7)		3 (25.0)	12 (60.0)		2 (50.0)	10 (66.7)	3 (27.3)	0 (0)	
Subjective memory decline			1.000			.159					.378
Yes	10 (58.8)	10 (62.5)		10 (76.9)	10 (50.0)		1(25.0)	11(73.3)	6 (54.5)	2 (66.7)	
No	7 (41.2)	6 (37.5)		3 (23.1)	10 (50.0)		3 (75.0)	4 (26.7)	5(45.5)	1 (33.3)	

Note: 1- These data were calculated on sample of N=14 due to missing data; 2-These data were calculated on sample of N=32 due to missing data.**p* value < .05 ; ***p* value < .001

Table 3

Health related QoL and illness perception, loneliness and resources (N=33)

Clinical data	**Global QoL**			**Overall health status**			**Disease specific QoL**				
	Positive N (%)	**Negative N (%)**	***p* value**	**Low N (%)**	**High N (%)**	***p* value**	**Good to excellent N (%)**	**Fair to good N (%)**	**Poor to fair N (%)**	**Very poor N (%)**	***p* value**
Illness Perception			.735			.015					.388
High thread	6(35.3)	7(43.8)		9 (69.2)	4 (20.0)		0 (0)	6 (40.0)	5(45.5)	2(66.7)	
Moderate thread	3(17.6)	4(25.0)		2 (15.4)	5 (25.0)		2 (50.0)	2(13.3)	2(18.2)	1(33.3)	
Low thread	8 (47.1)	5 (31.3)		2 (15.4)	11 (55.0)		2 (50.0)	7(46.7)	4(36.4)	0 (0)	
Acceptable symptom state			.490			.538					.361
Yes	0 (0)	2(12.5)		0 (0)	2 (10.0)		0 (0)	0 (0)	2 (18.2)	0 (0)	
Partial	10(58.8)	8 (50.0)		7(53.8)	11 (55.0)		2 (50.0)	9(60.0)	4(36.4)	3 (100)	
No	7 (41.2)	6 (37.5)		6(46.2)	7(35.0)		2 (50.0)	6 (40.0)	5 (45.5)	0 (0)	
Social support			1.000			.465					.549
Lack of support	11 (64.7)	10 (62.5)		7 (53.8)	14 (70.0)		2 (50.0)	11(73.3)	7 (63.6)	1 (33.3)	
No lack of support	6 (35.3)	6 (37.5)		6 (46.2)	6 (30.0)		2 (50.0)	4 (26.7)	4 (36.4)	2 (66.7)	
Meaning and spirituality			.227			1.000					.688
High	0 (0)	2 (12.5)		1 (7.7)	1 (5.0)		0 (0)	2(13.3)	0 (0)	0 (0)	
Low	17 (100)	14 (87.5)		12 (92.3)	19 (95.0)		4 (100)	13 (86.7)	11 (100)	3 (100)	
Loneliness			.491			.284					.294
Lonely	8(47.1)	10 (62.5)		9 (69.2)	9 (45.0)		3 (75.0)	6 (40.0)	6 (54.5)	3 (100)	
Not lonely	9 (52.9)	6 (37.5)		4 (30.8)	11 (55.0)		1 (25.0)	9 (60.0)	5 45.5)	0 (0)	
Health Literacy			.807			.447					.949
Adequate	2 (11.8)	3(18.8)		1 (7.7)	4 (20.0)		1 (25.0)	2(13.3)	1 (9.1)	1 (33.3)	
Limited	8(47.1)	8 (50.0)		8 (61.5)	8 (40.0)		2 (50.0)	7 (46.7)	6 (54.5)	1 (33.3)	
Marginal	7 (41.2)	5 (31.3)		4(30.8)	8 (40.0)		1 (25.0)	6 (40.0)	4 (36.4)	1 (33.3)	

Note: p value <0.05

Table 4

Health related QoL and psychological characteristics (N=33)

Psychological characteristics	**Overall health status**			**Disease specific QoL**				
	Low	**High**	***p* value**	**Good to excellent**	**Fair to good**	**Poor to fair**	**Very poor**	***p* value**
	N (%)	**N (%)**		**N (%)**	**N (%)**	**N (%)**	**N (%)**	
Psychological distress (HADS)			.431					.070
No	2 (15.4)	6 (30.0)		3 (75.0)	4 (26.7)	1 (9.1)	0 (0)	
Yes	11 (84.6)	14 (70.0)		1 (25.0)	11 (73.3)	10 (90.9)	3 (100)	
Anxiety (HADS)			.072					.005
No	3 (23.1)	12 (60.0)		4 (100)	9 (60)	2 (18.2)	0 (0.0)	
Yes	10 (76.9)	8 (40.0)		0 (0)	6 (40)	9 (81.8)	3 (100)	
Depression (HADS)			.005					.152
No	3 (23.1)	15 (75.0)		4 (100)	9 (60)	4 (36.4)	1 (33.3)	
Yes	10 (76.9)	5 (25.0)		0 (0)	6 (40)	7 (63.6)	2 (66.7)	
Depressive symptoms			.034					.848
Mild	4 (30.8)	16 (80.0)		4 (100)	9 (60)	5 (45.5)	2 (66.7)	
Normal	3 (23.1)	1 (5.0)		0 (0)	2 (13)	1 (9.1)	1 (33.3)	
Severe	3 (23.1)	1 (5.0)		0 (0)	2 (13)	2 (18.2)	0 (0)	
Moderate	3 (23.1)	2 (10.0)		0 (0)	2 (13.3)	3 (27.3)	0 (0)	
Perceived stress			1.000					.072
High	10 (76.9)	14 (70.0)		4 (100)	9 (60.0)	10 (90.9)	1 (33.3)	
Low	3 (23.1)	6 (30.0)		0 (0)	6 (40.0)	1 (9.1)	2 (66.7)	
Treatment burden			.720					.321
High burden	9 (69.2)	10 (50.0)		1 (25.0)	7 (46.7)	8 (72.7)	3 (100)	
Low burden	3 (23.1)	5 (25.0)		2 (50.0)	3 (20.0)	3 (27.3)	0 (0)	
Medium burden	1 (7.7)	4 (20.0)		1 (25.0)	4 (26.7)	0 (0)	0 (0)	
No burden	0 (0)	1 (5.0)		0 (0)	1 (6.7)	0 (0)	0 (0)	

Note: HADS - Hospital Anxiety and Depression Scale; *p* value < .05.

APPENDIX 3

Interview guide

Introduction to the study and the topic

The current study is planned in the frame of the ESCAPE project that investigates BCC effectiveness for the improvement of health-related QoL among elderly multimorbid patients with psychological distress in several EU countries, including Italy and Denmark.

Care Manager (CM), as a central figure of BCC, coordinates care delivery and provides necessary assistance to a patient. In this study, we would like to explore CM's perception of their role and functions in a frame of the ESCAPE BCC. In addition, we would like to explore CM's perception of the use of meta-algorithms for multi-morbidity (MAM) as a communication tool with GPs that aims to assist CMs and GPs in establishing main goals to focus on during the intervention considering patient's needs, preferences and psychological distress.

Table 1

Interview guide

Topic	*Guiding Questions*	*Possible Secondary Questions*
	CMs' perception of their role and function in a frame of the ESCAPE BCC	
General experience	Tell me about your experience performing CM tasks so far.	What has been challenging? How did you overcome these challenges? What has been surprising or unexpected? How your experience now is different from what you had at the beginning of the intervention?
Functions	Describe your experience in performing CM tasks/functions.	What has been challenging? How did you overcome these challenges? How your experience now is different from what you had at the beginning of the intervention? Tell me about functions, in your opinion, you have performed well.
	Tell me about your experience in delivering care via telephone.	What has been challenging? What made it hard to *proactively*[1] assist patients via telephone?

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[1] Proactively approach is explained to care managers during their training sessions. However, in case of unclarity the term will be explained to the interviewee.

		How did you overcome those difficulties? Tell me about your experience in integrating patients' preferences and medical needs.
Role	How you would describe CM's role in a frame of BCC, its central position and coordinating function between all stakeholders?	What has been challenging in coordinating patient care between stakeholders, such as the Specialist team, GPs, caregivers, external resources etc.?[2] How did you overcome these challenges? How your experience now is different from what you had at the beginning of the intervention?
Rapport	Tell me about your experience in establishing rapport at the beginning and later during the BCC intervention.	What has been challenging? How have you overcome these challenges? What could be done to improve CM-patient relationships in your opinion?
CMs' experience in utilizing MAM[3] for communication with GP and guidance of main goals establishment within BCC intervention		
General experience	Describe your experience of using MAM in communication with GPs.	What difficulties you have faced by using MAM? How have you overcome them?
Comprehensive/holistic case view	Tell me about your experience in goal setting based on MAM.	How MAM assists in needs and preferences inclusion in individual care plans? Considering that most of the needs-related information is gathered during contact 0, how

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[2] All stakeholders are pre-defined by the ESCAPE trail and CM are provided with guidelines regarding their communication with them. Each site might have differences regarding the involved stakeholders.

[3] In a frame of the ESCAPE BCC, a meta-algorithm for multimorbidity (MAM) is used in communication between GP and CM to report/present patient cases in a comprehensive way, including their needs & preferences and psychological distress. All CMs are familiar with the procedure through the training sessions.

	does this impact collection of “true” needs and preferences from the patients? How MAM assists in psychological distress consideration in the individual care plan?