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“BARRIERS FOR CARDIAC REHABILITATION IN HEART FAILURE:
HOW TO IMPROVE ADHERENCE”

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This work is dedicated to my parents Neilde e José,

To my master of life Daisaku Ikeda,

To my children pet bob (in memorian), pink, titica e simba

And my love Jules.

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RESUMO

Introdução: Apesar da disponibilidade de terapias farmacológicas e de dispositivos para o tratamento da insuficiência cardíaca (IC), os doentes com IC ainda apresentam um mau prognóstico e uma qualidade de vida reduzida. Modificações no estilo de vida, a reabilitação cardíaca (RC) e exercício físico regular, ajudam a controlar os sintomas da IC e melhorar a função cardíaca. No entanto, apesar de todas as evidências científicas e recomendações clínicas, a RC é subutilizada no tratamento da IC. As razões para a subutilização dos programas de RC são multifatoriais e incluem fatores relacionados com o sistema de saúde, os profissionais de saúde ou ainda barreiras relacionadas ao doente. É importante identificar estas barreiras para aumentar a participação e adesão aos programas de RC de modo a garantir que todos os que possam se beneficiar deste tipo de programa tenham a oportunidade de participar. Desta forma, a RC domiciliária isoladamente ou em combinação com a RC supervisionada, tem o potencial de abordar algumas barreiras, como flexibilidade de horário, distância do centro de RC, custos e a preferência do doente. Além disso, o maior grau de auto monitorização exigido em programas domiciliários pode promover uma transição favorável para a mudança comportamental sustentável e o autocuidado da doença. A adesão a longo prazo ao exercício físico após a fase II da RC pode ser desafiadora, mas é fundamental para manter a saúde cardiovascular e reduzir o risco de futuros eventos cardíacos. Assim, considerando a importância dos programas de RC no tratamento dos doentes com IC, a baixa acessibilidade e adesão a esse tipo de programa, bem como a adesão subótima em longo prazo, é preciso entender os motivos dessa subutilização no contexto da população portuguesa.

Objetivo: No presente trabalho propomos-nos: i) descrever e comparar as barreiras à participação num programa de RC hospitalar versus domiciliar em doentes com IC num hospital público em Portugal; ii) investigar a relação entre as barreiras reportadas e a adesão ao programa de RC; iii) verificar a efetividade de um programa de RC domiciliário em relação a adesão a longo prazo à atividade física e aos níveis de aptidão física após um programa de RC fase 2; iv) comparar os efeitos a longo prazo de uma intervenção de RC domiciliária versus uma intervenção de RC hospitalar; e v) propor um programa comunitário especializado de RC fase III visando auxiliar doentes cardíacos a alcançarem um estilo de vida saudável, a controlar os fatores de risco cardiovascular e promover o bem-estar após a fase II de RC.

Métodos: Para alcançar os objetivos propostos, avaliamos 87 doentes com IC no Estudo I e 54 pacientes com IC no Estudo II. No estudo I, foi utilizado o questionário de Barreiras na Reabilitação Cardíaca para avaliar a perceção dos doentes em relação ao grau em que diferentes barreiras afetam sua participação no programa de RC. Além disso, foram coletados dados de adesão dos registos das sessões de exercícios e da monitorização de frequência cardíaca. No Estudo II, os doentes foram avaliados quanto à atividade física (IPAQ versão curta e o monitor de frequência cardíaca, modelo POLAR M200) e aptidão física (teste de caminhada de 6 minutos, teste de 8-foot-up-and-go, teste de força de preensão manual e teste de sentar e levantar por 30 segundos). O Estudo III é um protocolo de fase III para ser implementado dentro da comunidade

Resultados: No Estudo I, os nossos dados indicam que "outros problemas de saúde" são a principal barreira à RC para doentes com IC na população estudada. Comparando com o grupo RC hospitalar, os doentes do grupo RC domiciliário identificaram duas principais barreiras como principais, nomeadamente, "mau tempo" e "tenho pouco tempo", mas isso não se refletiu nas taxas de adesão. No Estudo II, nossos dados sugerem que o programa domiciliar não resultou em melhor adesão à atividade física a longo prazo ou níveis de aptidão física em comparação ao programa hospitalar. Por fim, no Estudo III, propomos a implementação de um programa de RC fase III na comunidade, com alocação em grupos de acordo com a preferência do doente, a fim de abordar desafios de saúde e sociais não atendidos relacionados à manutenção após a fase II de RC.

Conclusões: Os nossos dados sugerem que, após identificar as barreiras relacionadas à participação e adesão à RC, programas individualizados que incorporem as barreiras específicas do doente poderão ter um impacto na participação nestes programas. Além disso, 12 semanas de um programa de RC domiciliária ou hospitalar parecem não ser suficientes para promover uma transição para uma mudança de comportamento sustentável no tempo. Por fim, são necessários novos programas especializados de RC de fase III baseados na comunidade para ajudar os doentes cardíacos a alcançarem um estilo de vida saudável e sustentável, auxiliar no controle dos fatores de risco cardiovascular e promoverem o bem-estar após a RC de fase II.

Palavras-chave: reabilitação cardíaca, insuficiência cardíaca, domiciliar, barreiras, adesão, efeitos a longo prazo, doentes cardíacos, fase III, comunidade.

ABSTRACT

Introduction: Despite a variety of pharmacological and device therapies for heart failure (HF), patients still have a poor prognosis and quality of life. Lifestyle modifications, cardiac rehabilitation (CR) and regular exercise, have been shown to help manage HF symptoms and improve cardiac function. However, despite all the scientific evidence and clinical recommendations, CR is underutilized in the treatment of HF. The reasons for the underutilization of CR programs are multifactorial and include health system, health professionals or patient barriers. It is important to address these barriers to increase participation and adherence to ensure that everyone who could benefit from CR has the opportunity to participate. In light of this, home-based CR (HBCR) alone or in combination with clinical-based CR (CBCR), have the potential to address some barriers such as schedule flexibility, time commitment, travel distance, cost and patient preference. In addition, the higher degree of self-monitoring/management required in home-based programs, may promote a favorable transition to sustainable behavioral change and disease self-management. Long-term adherence to exercise training after CR phase 2 can be challenging, but it is critical to maintaining cardiovascular health and reducing the risk of future cardiac events. Thus, considering the importance of CR programs in the treatment of patients with HF, the low accessibility and adherence to this type of program, as well the long-term adherence, it is necessary to understand the reasons for this underutilization in the context of the Portuguese population.

Objective: In the present work we propose: i) to describe and compare the barriers to participation in a clinical versus home-based CR program in patients with HF in a public hospital in Portugal; ii) to investigate whether these barriers were related to adherence to the CR program; iii) to assess the effectiveness of the home-based CR on exercise adherence and physical fitness after phase II CR in HF patients; iv) to compare long-term effects of a home-based vs clinical-based CR intervention; and v) to propose the implementation of a specialized community phase III CR program to help cardiac patients achieve a healthy lifestyle, manage optimal cardiovascular risk factors, and promote wellness after phase II CR.

Methods: To achieve the proposed objectives, we evaluated 87 patients with HF in Study I and 54 patients with HF in Study II. In study I, the Barriers to Cardiac Rehabilitation Scale questionnaire was used to assess patients' perception of the degree to which different barriers affected their participation in a CR program. In addition, adherence data were collected from exercise session records and the heart rate monitor device. In Study II, patients were assessed for physical activity (IPAQ short version and the heart rate monitor, model POLAR M200) and physical fitness (6-minute-walking test (6MWT), 8-foot-up-and-go test, handgrip and 30-second sit-to-stand test). Study III is a phase III CR protocol to be implemented within the community.

Results: In Study I, our data indicate that other health problems are the main barrier for patients with HF. Comparing with CBCR group, the HBCR participants rated two main barriers significantly higher, such as “bad weather” and “I have little time”, but it not reflected in adherence rates. In Study II, our data suggests that HBCR program did not resulted in better adherence to long-term physical activity or fitness levels compared with the CBCR intervention. Finally, in Study III, we propose a phase III CR program within the community, with group allocation according to preference, to respond to unmet health and social challenges regarding maintenance after phase II CR.

Conclusions: Our data suggest that after identifying barriers related with CR participation and adherence, an individualized CR programs that incorporates patient's-specific barriers would impact on CR participation. In addition, 12 weeks of a HBCR or CBCR program appears to be not enough to promote a transition to sustainable behavior change over time. Finally, new a specialized community-based phase III CR programs are needed to help cardiac patients achieve a sustainable healthy lifestyle, manage optimal cardiovascular risk factors, and promote wellness after phase II CR.

Key words: cardiac rehabilitation, heart failure, home-based, barriers, adherence, long-term effects, cardiac patients, phase III, community.

LIST OF ABBREVIATIONS

6MWT	6-minute walk test
8FUG	8-foot and go test
AAS	acetylsalicylic acid
ACC	American College of Cardiology
ACE	angiotensin-converting enzyme
ACE-i	angiotensin-converting-enzyme inhibitor
AF	atrial fibrillation
AHA	American Heart Association
ARB	angiotensin II receptor blocker
BMI	body mass index
BNP	b-type natriuretic peptide
CAD	coronary artery disease
CBCR	clinical-based cardiac rehabilitation
CHUP	Cardiac Rehabilitation Unit of the Centro Hospitalar Universitário do Porto
CI	confidence intervals
CPET	Cardiopulmonary exercise test
CR	cardiac rehabilitation
CRBS	Cardiac Rehabilitation Barriers Scale
CRT	cardiac resynchronization therapy
CV	cardiovascular
CVD	cardiovascular diseases
E/e'	diastolic velocity of the mitral valve annulus
ECG	electrocardiogram
EPICA	Epidemiology of Heart Failure and Learning
ESC	European Society of Cardiology
EXIT-HF	Exercise Intervention in Heart Failure
ExT	exercise training
FADEUP	Faculty of Sport at Porto University
HADS	Hospital Anxiety and Depression Scale
HBCR	home-based cardiac rehabilitation

HF	heart failure
HF-ACTION	A Controlled Trial Investigating Outcomes of Exercise Training
HFmrEF	HF with mid-range ejection fraction
HFpEF	HF with preserved ejection fraction
HFrEF	HF with reduced ejection fraction
HR	heart rate
HyCR	hybrid CR
ICD	Implantable cardioverter-defibrillator
IPAQ-SF	International Physical Activity Questionnaire
IQR	interquartile ranges
LVEF	left ventricular ejection fraction
MI	myocardial infarction
MLHFQ	Minnesota Living with Heart Failure questionnaire
MVPA	moderate-to-vigorous physical activity
NYHA	New York Heart Association
NT-proBNP	N-terminal pro-B-type natriuretic peptide
OR	odds ratio
PA	physical activity
QoL	quality of life
SBP	systolic blood pressure
SD	standard deviation
SF-36	36-Item Short-Form Health Survey
SPIRIT	Standard Protocol Items Recommendations for Interventional Trials
SPSS	Statical Package for the Social Sciences
STS-30	30-second sit to stand test
VM	vector magnitude
VO_2	oxygen consumption

CHAPTER I

GENERAL INTRODUCTION

1. HEART FAILURE OVERVIEW

1.1 Definition

Heart failure (HF) is a clinical syndrome caused by abnormalities in cardiac structure and/or function, which results in a reduced cardiac output and/or elevated intracardiac pressures at rest and/or during stress (Bozkurt B Fau - Hershberger et al.; McDonagh et al., 2021). Heart failure is characterized by symptoms such as breathlessness, ankle swelling, fatigue, exercise intolerance, and signs such as peripheral oedema and high blood pressure. In addition, these patients have reduced exercise capacity and quality of life, limiting their ability to perform simple daily activities.

Heart failure is one of the leading causes of morbidity and mortality worldwide, with exponential increase (Metra & Teerlink, 2017), and remains an important clinical and public health problem, affecting more than 26 million people across the globe (Fonseca, Brás, Araújo, & Ceia, 2018). The increase in the number of people living with HF may be associated with population aging, global population growth and improved survival (Groenewegen, Rutten, Mosterd, & Hoes, 2020). In Portugal, the HF prevalence is expected to increase by 28% and mortality by 73% by 2036 due to the aging of the population (Gouveia et al., 2019). Despite a variety of pharmacological therapies and devices for HF, patients still have poor prognosis and long-term quality of life (Packer & Metra, 2020).

1.2 Classification

According to the current guidelines of the European Society of Cardiology (ESC), HF is categorized according to left ventricular ejection fraction (LVEF) into HF with reduced ejection fraction (HFrEF), when there is a significant reduction in left ventricular (LV) systolic function (LVEF ≤40%, known as HFrEF; also referred to as systolic HF); HF with preserved ejection fraction (HFpEF), when, in addition to presenting signs and symptoms of HF and evidence of structural and/or functional cardiac abnormalities, there is a preserved LVEF (LVEF ≥50%, known as HFpEF;); and HF with mildly reduced ejection fraction (HFmrEF) when there is a mild reduction in systolic function, characterized by a LVEF between 41 to 49% (McDonagh et al., 2021).

Heart failure can also be classified based on disease progression or based on symptom severity. The disease progression is classified by the American Heart Association (AHA) and the American College of Cardiology (ACC) in stages A to D (Bozkurt B Fau - Hershberger et al., 2021). Stage A patients include those at risk of developing HF, stage B include patients with structure heart disease but without signs and symptoms, stage C those with HF symptoms and stage D patients who have advanced HF (Bozkurt B Fau - Hershberger et al., 2021).

Symptom severity can be assessed using the New York Heart Association (NYHA) functional classification system based on how much they are limited during physical activity (PA) class I to IV) (McDonagh et al., 2021). In class I, the patient does not have limitations in PA and common PA does not cause fatigue, palpitation, dyspnea or anginal pain. In class II, the disease results in a slight limitation of PA. Patients are comfortable at rest, but common PA results in fatigue, palpitation and dyspnea. In class III, patients have marked limitations of PA. They are comfortable just at rest, but in common everyday movement they feel fatigue, palpitation, dyspnea or anginal pain. Lastly, in class IV, patients cannot perform any PA without discomfort. Symptoms of cardiac insufficiency can be observed even at rest, if any PA is undertaken, discomfort is increased.

1.3 Epidemiology

The concept of HF syndrome emerged as an epidemic approximately 25 years ago (Groenewegen et al., 2020). Today, HF is considered a global pandemic and its prevalence is high, affecting at least 64 million people worldwide (GBD, 2018). Even with advances in treatments and prevention approaches, health expenditures on HF are considered high and tend to increase exponentially with aging and population growth (Groenewegen et al., 2020). The mortality and morbidity rates are still high and quality of life low (Nair, 2020). It is important to emphasize that there are geographic variations according to the etiology and specific clinical features of patients with HF, and these differences change the rates of prevalence, incidence, mortality and morbidity (Savarese & Lund, 2017).

Analyzing the disease rates in developed countries, and when analyzed and adjusted for age, it seems to have reduced the increase in HF, probably due to the improvement and effectiveness in the treatment of the disease (McDonagh et al., 2021). However, there is an increase in the absolute number of HF cases, that is, a general increase is growing, probably due to the increase in the aging rate as well as in the population (Savarese & Lund, 2017).

Currently, the incidence of global HF is estimated to be approximately 1-20 cases per 1.000 person-years, with a prevalence ranging from 1-3% among the adult population (Savarese et al., 2023). In Portugal, the Epidemiology of Heart Failure and Learning (EPICA) study reported a prevalence of HF in the adult population of 4.4%, with this prevalence being higher at advanced ages (7.6% in the 60-69 age group and 16.1% for those aged >80 years) (Fonseca et al., 2018).

The prevalence of HF increases with age, corresponding to approximately 1% for those aged <55 years to >10% for those aged 70 years or older (van der Wal, van Veldhuisen, Veeger, Rutten, & Jaarsma, 2010). In a middle-aged population, men develop HF more often and at a younger age than women. However, women are at higher risk for developing HFpEF, with atrial fibrillation being a specific risk factor for this population (McDonagh Ta Fau - Metra et al., 2021). Based on studies conducted primarily on hospitalized patients, it is commonly believed that approximately 50% of individuals have HFrEF, while the remaining 50% have HFpEF or HFmrEF (McDonagh Ta Fau - Metra et al., 2021; Meyer et al., 2015). Compared with HFpEF individuals, HFrEF patients were younger, mostly male, more likely to have an ischemic etiology, but less likely to have hypertension or atrial fibrillation (Meyer et al., 2015). The HFmrEF group resembled the HFrEF group in some characteristics, including age, sex, and ischemic etiology, but had less left ventricular and atrial dilatation (Li et al., 2021). Patients with HFpEF are older, most are women and, in relation to comorbidities, there is a higher prevalence of hypertension and valvular etiology (Li et al., 2021).

1.4 Etiology

It is considered a challenge to determine a unique and specific origin for the individual's HF condition, as the consequence of the chronic stage of various diseases ends up leading to impairment of cardiac function, resulting in a diagnosis of HF (Groenewegen et al., 2020).

The etiology of HF varies by region (demographic condition) (McDonagh et al., 2021). In developed countries, hypertension and coronary artery disease (CAD) are the predominant factors for the development of HF (GBD, 2018). Overall, the most common causes of HF, according to ESC 2021 (McDonagh et al., 2021) are: CAD, hypertension, valve disease, arrhythmias, cardiomyopathies, congenital heart disease, infectious, drug-induced, infiltrative, heart disease storage, endomyocardial disease, pericardial disease, metabolic and neuromuscular disease. In addition, the importance of counseling cardiovascular risks and diseases in this category, mainly diabetes mellitus, systemic hypertension, coronary artery disease, atrial fibrillation, myocardial infarction and systolic dysfunction asymptomatic left ventricular valve as a way to reduce the incidence of HF.

1.5 Diagnostic and treatment

Regarding the diagnosis of HF, it requires the presence of symptoms (e.g., breathlessness, ankle swelling, and fatigue) and/or signs (e.g., elevated jugular venous pressure, pulmonary crackles, and peripheral edema) of HF and objective evidence of cardiac functional and/or structural alterations (Löfström et al.; McDonagh et al., 2021)

Typically, HF is common in patients with a history of myocardial infarction, arterial hypertension, coronary arterial disease, diabetes mellitus, alcohol misuse, chronic kidney disease, cardiotoxic chemotherapy, and in those with a family history of cardiomyopathy or sudden death (McDonagh et al., 2021).

To confirming or excluding the diagnosis of HF, some tests are recommended by the ESC (McDonagh et al., 2021), such as: i) electrocardiogram (ECG) (a normal ECG makes the diagnosis of HF unlikely); ii) blood test to check the levels of natriuretic peptide when available. A plasma concentration of B-type natriuretic peptide (BNP) <35 pg/mL, N-terminal pro-B-type natriuretic peptide (NT-proBNP) <125 pg/mL, or mid-regional pro-atrial natriuretic peptide <40 pmol/L68 make a diagnosis of HF unlikely. In addition, basic investigations such as serum urea and electrolytes, creatinine, full blood count, liver and thyroid function tests are recommended to differentiate HF from other conditions; iii) echocardiography for the assessment of cardiac function; and iv) a chest X-ray to investigate other potential causes of breathlessness (e.g., pulmonary disease) is recommended. Treatment for HF is dependent on the underlying cause and on the severity, and typically involves a combination of medications, surgery or medical devices, heart transplant and lifestyle changes.

The therapy aims to decrease the rate of hospitalization and mortality as well reduce symptoms, improve health-related quality of life and functional status (Ponikowski P Fau - Voors et al., 2016; van der Wal et al., 2010). To manage HF symptoms and improve cardiac function, medications such diuretics, angiotensin-converting enzyme (ACE) inhibitors, beta blockers, and angiotensin receptor blockers are frequent used (McDonagh et al., 2021), However, surgery or medical devices such as implantable cardioverter defibrillators may be needed in some cases of HF (McDonagh et al., 2021), and in severe cases where other treatments are not effective, a heart transplant may be considered (Tomasoni et al., 2022)

Lifestyle changes in HF treatment include cardiac rehabilitation (CR) and regular exercise, cessation of smoking, limiting alcohol consumption and sodium intake and adhere to a healthy diet. Lifestyle modifications has been shown to help to manage symptoms of HF and improve cardiac function (Camafort, Park, & Kang, 2023).

Cardiac rehabilitation has been used as an essential component in the treatment of HF patients (McDonagh et al., 2021). However, despite all the scientific evidence and clinical recommendations, CR is underused in the treatment of HF (Humphrey, Guazzi, & Niebauer, 2014).

2. CARDIAC REHABILITATION

Cardiac rehabilitation is a comprehensive multidisciplinary intervention that aims to limit the physiological and psychological effects of cardiac illness, enhance the psychosocial and vocational status, and promote lifestyle chances after an acute cardiac event or in the context of chronic cardiovascular disease (such as angina or heart failure) (Abreu et al., 2018; Ambrosetti et al., 2020).

In order to achieve these benefits, a multidisciplinary approach is required, which involve patient assessment and risk stratification, management and control of cardiovascular risk factors, exercise training, dietary advice, physical activity counselling, psychosocial support and vocational assistance (Ambrosetti et al., 2020). The core components of CR are present in Figure 1. Consequently, the CR program should be delivered by a multidisciplinary team comprising of professionals such as cardiologists, physical medicine specialist, nurse, physiotherapist and/or exercise physiologist nutritionists and psychologist/psychiatrist (Abreu et al., 2018; Ambrosetti et al., 2020; Balady et al., 2007).

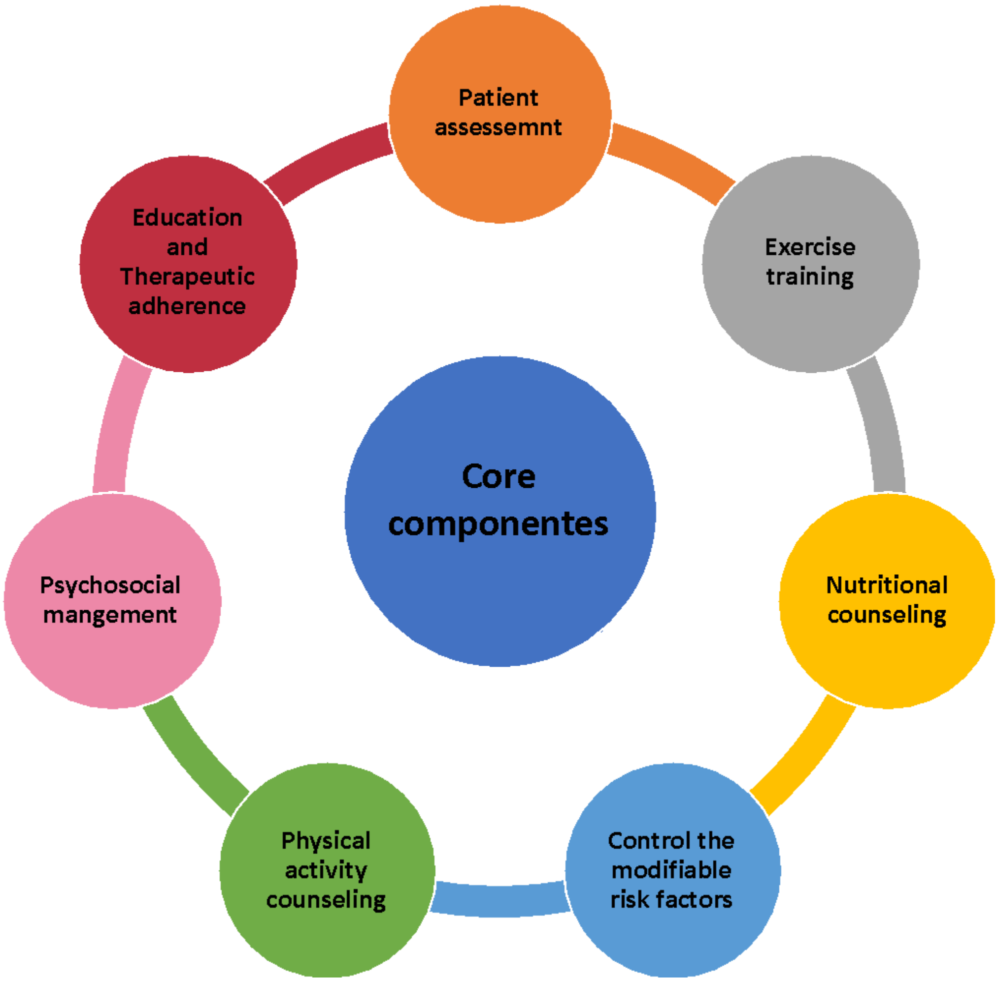

Figure 1: Core components of a cardiac rehabilitation program.

CR program is divided into three phases. Phase 1, called inpatient phase, begins soon after a cardiovascular event or a cardiac intervention procedure when the patient is still in hospital (Ambrosetti et al., 2020). At this time, nurses and physiotherapists are responsible for the early progressive mobilization aimed to improve the capacity to perform basic movements and limiting deconditioning (Abreu et al., 2018). Phase 1 also involve education about the disease, risk factors counselling, and the referral to phase 2. Phase 2, the outpatient phase, consists of a structured, multidisciplinary, supervised program performed at hospital facilities, that can also be carried out in other models, such as home-based or a hybrid model (Thomas et al., 2019). This phase usually lasts from 8 to 12 weeks, and can last up to 24 weeks, where patients are monitored during the exercise training session by physiotherapists and/or exercise physiologist with an individualized exercise training program (Balady et al., 2007). The exercise training program should include aerobic and resistance training with the aim to promote functional independence and preparing patients to return to their usual activities. Phase 3, the long-term phase, starts after phase 2 and should last for the rest of the patient’s life (Abreu et al., 2018). It aims to increase and maintain the gains obtained in the previous phase, with emphasis on self-monitoring and independence. Patients are encouraged to continue exercise and maintain an active lifestyle. To ensure cardiovascular health and proper medication management, it is recommended that individuals attend outpatient visits with physician specialists. These visits not only provide an opportunity for monitoring but also allow for promoting healthy lifestyle changes and intervening when necessary to prevent relapse (McMahon, Ades, & Thompson, 2017).

2.1. Cardiac Rehabilitation in Heart Failure

In patients with HF, numerous studies have demonstrated the efficacy of CR or exercise training regardless of its underlying phenotype (Edwards & O'Driscoll, 2022; R. S. Taylor, Long, et al., 2019). Recognized in the literature as an essential component in the treatment of patients with HF, exercise-based cardiac rehabilitation improves patients' quality of life, functional capacity and reduces the risk of hospitalization and mortality (Chen & Li, 2013; Keteyian et al., 2012).

In patients with HF with reduced ejection fraction the evidence is robust. In the HF-ACTION, patients exercised during 36 weeks at hospital facilities followed by home-based exercise training were compared with usual care alone

(O'Connor et al., 2009). The results showed that exercise training improves exercise capacity showed by an improvement on oxygen consumption (VO_2) at 3 months, and after adjustment for covariates, there was a reduction in mortality (O'Connor et al., 2009). A recent meta-analysis demonstrated improvements in different parameters after an exercise training program such as maximal (VO_2) and submaximal (distance at the six-minute walking test (6MWT)) exercise capacity, quality of life (Minnesota Living with Heart Failure questionnaire (MLHFQ)), and cardiac function (increase on left ventricle ejection fraction and reduction on BNP/NTproBNP levels) (Edwards & O'Driscoll, 2022). On the other hand, no significant changes were found in hospitalization, all-cause mortality or composite endpoints.

In HFpEF patients, there is just a few studies that evaluated the impact of CR or exercise training. A meta-analysis which included 11 studies with HFpEF patients demonstrated significant improvements in peak VO_2, 6MWT, MLHFQ and cardiac function (E/e' ratio) (Edwards & O'Driscoll, 2022).

Evidence from CR programs have also great improvements in HF patients. Taylor and collaborators analyzed 44 clinical trials which included 5.783 HF patients with both phenotypes, comparing CR with control group (R. S. Taylor, Long, et al., 2019). Although CR did not reduce the risk of all-cause mortality, it was able to reduce all-cause hospitalization, HF-specific hospitalization, besides the improvements on MLHFQ questionnaire overall scores. It is important to highlight that no evidence of differential effects across different models of delivery, including center- versus home-based programs, were found.

Despite all the scientific evidence and clinical recommendations, CR is underused in the treatment of HF patients (Humphrey et al., 2014). It is estimated that in Europe only 20% of individuals with HF have access to a CR program (Bjarnason-Wehrens et al., 2010). In Portugal, HF is responsible for around 14.5% of admissions to CR programs (Fontes, Vilela, Durazzo, & Teixeira, 2021).

2.2. Barriers to cardiac rehabilitation

The reasons for the underutilization of CR programs are multifactorial and encompass healthcare system-, health professional-, or patient-level barriers (Sérvio et al., 2019) (Table 1).

Table 1. Types of Barriers in Cardiac Rehabilitation

Healthcare system
Lack of specialized centers
Non-participation
Access to specialized programs
Health professional
No referral
Ignorance of benefits or specialized locations
Strength of recommendation at the time of referral
Patient-level
Refusal to participate
Lack of motivation
Difficulties in reconciling the program with work
Financial difficulties for traveling and paying for the sessions
and even the social context

Some common healthcare system-related barriers to cardiac rehabilitation include: the lack of structured CR programs, the weak referral process, the limited financial incentives, insurance coverage and reimbursement issues, and hospital characteristics (e.g., size and geographic localization) (Grace et al., 2008; Sérvio et al., 2019; G. H. Taylor, Wilson, & Sharp, 2011). In addition, the fragmented care where patients may receive care from multiple providers or healthcare systems, can make it difficult to coordinate referrals and ensure continuity of care.

Health professional-related barriers can also impact access to cardiac rehabilitation programs. These barriers may include lack of knowledge and motivation, limited time, lack of professional training, post-discharge planning, and inter-professional communication.

Patient-level barriers to CR are factors that affect their education and empowerment, adherence to healthy lifestyle, and adherence to these programs. Some common patient-level barriers to CR include lack of knowledge about the disease, lack of motivation, physical limitation, lack of social support, inconvenient localization, transport difficulties, financial cost, poor psychological wellbeing and competing work commitment. In the study by (Xie, Chen, & Liu, 2022) who investigated the barriers to phase 2 CR among patients with coronary disease, found the main ones to be: distance, transportation, cost and time constraints. Similar results were found in the study by (Bakhshayeh, Sarbaz, Kimiafar, Vakilian, & Eslami, 2021) who found among the most effective barriers, problems with transportation, distance to the CR site and costs for displacement.

Overall, it is important to address these barriers to ensure that everyone who could benefit from CR can participate. Improving CR participation requires a multi-level approach that encompasses legislation, international and national guidelines, and local strategies (Clark et al., 2013; Nieuwlaat, Schwalm, Khatib, & Yusuf, 2013). Healthcare providers can help by educating patients about the benefits of CR, providing information on available programs, and working with insurance companies to ensure that the costs are covered (McIntosh et al., 2017). Additionally, providers can work to make CR programs more accessible by offering remote options, providing transportation assistance, and ensuring that program materials are culturally and linguistically appropriate.

Addressing professional-related barriers may require additional education and training for healthcare professionals, as well as changes to the healthcare system to support and incentivize the use of CR programs. It is important for healthcare providers to understand the benefits of CR and to prioritize their use as a key component of cardiovascular care. Additionally, healthcare providers can work to improve communication with patients about CR programs and the referral process and can collaborate with other healthcare professionals to ensure that patients receive comprehensive care that includes CR when appropriate.

To address the patient-level barriers may require individualized support and education to help patients overcome their concerns and feel motivated to participate in CR programs (Chindhy, Taub, Lavie, & Shen, 2020). Healthcare providers can work with patients to develop personalized care plans that consider their individual needs and preferences and can provide resources and support to help patients overcome barriers such as lack of transportation or social support (Chindhy et al., 2020). Additionally, providers can work to make CR programs more accessible and culturally appropriate for all patients.

Over the past years, home-based CR have been used as an option to overcome barriers of traditional CR (Anderson et al., 2017).

2.3 Home-based cardiac rehabilitation

Home-based interventions, either alone or in combination with clinic-based CR (hybrid CR), have the potential to address some barriers such as schedule flexibility, time commitment, travel distance, cost, and patient preference (Chindhy et al., 2020). The European Guidelines on cardiovascular diseases prevention highlight that home-based programs with and without telemonitoring is a promising strategy to increase CR participation and supporting behavioral change (McDonagh et al., 2021). Recent technological advances made possible and increasingly affordable to monitor at distance the frequency and intensity of exercise; telemonitoring allows the individual tailoring of exercise prescription and distance coaching, as well as enhancing adherence. Some studies had promisingly demonstrated the advantages of this modality of delivering exercise (Imran et al., 2019; Zwisler et al., 2016). Home-based telerehabilitation was showed to be well accepted, safe, effective and has high adherence among patients with HF, including those with cardiovascular implantable electronic devices (Piotrowicz et al., 2015). In addition, the HF-ACTION study demonstrated that home-based CR with a simple monitorization, as heart rate monitors, is also safe and effective (O'Connor et al., 2009). A meta-analyze which include 31 randomized controlled trials with a total of 1791 HF participants, reported that home-based exercise can improve functional capacity and quality of life when compared to usual care, and have similar improvements compared with clinic-based CR (Imran et al., 2019).

Beyond the front mentioned benefits, home-based CR was also reported to be a cost-effective intervention compared with usual care alone in patients with HFrEF, which appears to be mainly driven by a reduction in HF-related hospitalizations (R. S. Taylor, Sadler, et al., 2019). In addition, home-based telerehabilitation program was showed to be a cost-saving intervention compared with a traditional clinic-based CR program (Hwang et al., 2019). Considering that CR programs are a cost-effective intervention which results in clinical improvements, and that these benefits are independent of program type (clinic or home-based settings), home-based CR may be an alternative to improve CR accessibility and patient´s adherence.

However, it is important to note that home-based programs may not be suitable for all patients, particularly those who require closer medical supervision or who have limited access to equipment or resources. Therefore, healthcare providers should carefully evaluate patients' needs and preferences when considering home-based CR programs as an option.

2.4. Maintenance after phase II CR

Following phase II CR program completion, patients are encouraged to maintain the exercise training routine on their own to preserve the achieved health benefits. Long-term adherence to exercise training after phase 2 CR can be challenging, but it is critical for maintaining cardiovascular health and reducing the risk of future cardiac events (Tilgner et al., 2022).

However, most patients are unable to maintain their physical training routine and return to a sedentary lifestyle. Data from the literature show that less than 50% of patients continue to exercise on their own after the completion of CR (Hansen, Dendale P Fau - Raskin, et al., 2010). Furthermore, it is shown that exercise adherence is reported in only 30-60% after CR completion by the sixth month, and only 20–50% of patients continue exercising on their own by the 12th month (Daly et al., 2002; Dolansky, Stepanczuk, Charvat, & Moore, 2010; Hansen, Dendale, et al., 2010). Poor adherence to exercise training results in reversion of the obtained benefits (e.g., physical fitness and worsening of cardiovascular diseases (CVD) risk profile) (Giallauria et al., 2006; Hansen, Dendale, et al., 2010; Volaklis, Douda, Kokkinos, & Tokmakidis, 2006) and limits the potential of CR to change the patient prognosis. This difficulty in maintaining or increasing post-CR physical activity levels can be attributed to multiple factors, including lack of time and motivation, loss of social support and low self-efficacy (Fletcher et al., 2018; Hately & Mandic, 2019; Mandic et al., 2015).

Home-based interventions, alone or in combination with clinically based CR, have the potential to address some of these issues. According to the European Guidelines for the Prevention of Cardiovascular Diseases, home-based programs with and without telemonitoring are a promising strategy to increase participation in CR and support behavioral change (McDonagh et al., 2021). Furthermore, they claim that the greater degree of self-monitoring/management required in home-based programs may promote a favorable transition to sustainable behavioral change and disease self-management.

However, the potential of home CR to preserve the health benefits achieved after phase II CR programs in patients with HF is unknown.

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CHAPTER II

AIMS

AIMS

Taking in account the above brief review, the aims of this thesis according to each original study were:

Study 1:

- To describe and compare the barriers to participation in a clinical versus home-based CR program in patients with HF in a public hospital in Portugal.
- To investigate whether these barriers were related to adherence to the CR program.

Study 2:

- To verify the effectiveness of home-based CR on exercise adherence and physical fitness after phase II CR in HF patients.
- To compare home-based vs clinic-based CR intervention.

Study 3:

A study protocol was design to respond to the unmet health and social challenges regarding exercise maintenance after phase II CR aimed to:

- Implement a specialized community phase III CR program to help cardiac patients achieve a sustainable healthy lifestyle, manage optimal cardiovascular risk factors, and promote wellness after phase II CR.

CHAPTER III

ORIGINAL STUDIES

STUDY I

A COMPARISON OF BARRIERS TO ADHERENCE IN CLINIC AND HOME-BASED CARDIAC REHABILITATION IN PATIENTS WITH HEART FAILURE

ABSTRACT

Introduction: Despite the evidence regarding the benefits of cardiac rehabilitation (CR) by heart failure (HF) patients, the enrolment and adherence to CR in this population remains suboptimal. Some adherence barriers reported in studies performed in other countries were geographic location, transportation, financial factors, difficulties in reconciling the program with work, and bad weather. However, the heterogeneity of the populations studied limits the external validity of available evidence to our national context.

Aims: To describe and compare barriers to the participation in a clinic (CBCR) versus home-based CR (HBCR) program, and to investigate whether these barriers are related to adherence in HF patients in a tertiary hospital in Portugal.

Methods: This study is a sub-analysis of the EXIT-HF study with HF patients who were randomized to a CBCR or HBCR program. After 12-weeks of a CR program, patients answered the Cardiac Rehabilitation Barriers Scale and adherence data were collected from exercise sessions records and from heart rate monitor.

Results: Overall, the highest scoring barriers were “other health problems” (48.2%) and “lack of energy” (32.1%). Both groups reported concomitant medical problems as the main barrier. The HBCR participants rated two main barriers significantly higher, such as “bad weather” (2.07±1.65 vs 1.06±0.24 points; p=0.002) and “I have little time” (1 .59±1.37 vs 1.09±0.52 points; p=0.002). The adherence to CR program was 91% for the CBCR and 82% for the HBCR group (p>0.05). The main causes of non-adherence at HBCR group were “other health problem” (80%) and “feel that don't have energy to exercise” (70%). Low attendance was significantly correlated with “transport problems” among CBCR participants (r= -0.351; p=0.045), and with the “feeling of do not have energy” among HBCR participants (r= -0.402; p=0.003). The higher the score of the barriers, the lower the odds of the participant having adhered to the CR program (OR = 0.776; CI 95% = 0.619-0.972, p = 0.028).

Conclusions: Other health problems was the main barrier reported by HF patients regardless of the context in which the CR program was performed. Despite that, adherence to both CR programs were high. The early recognition and treatment of concomitant medical problems should be an important strategy for increase CR adherence.

Keywords: cardiac rehabilitation, heart failure, barriers, adherence.

INTRODUCTION

It is estimated that heart failure (HF) affects more than 26 million people worldwide (Ambrosy et al., 2014). In Portugal, the EPICA study reported a prevalence of HF in the adult population of 4.4%, with this prevalence being higher at advanced ages (7.6% in the 60-69 age group and 16.1% for those aged >80 years) (Fonseca, Bras, Araujo, & Ceia, 2018). Despite all the therapeutic progress recorded, HF is still characterized by high rates of morbidity and mortality, low quality of life and very significant health care costs (Choi, Park, & Youn, 2019).

Exercise-based cardiac rehabilitation (CR) has been used as an essential component in the treatment of HF patients (Flynn et al., 2009; Ponikowski et al., 2016). Studies have shown that a CR program improves symptoms, functional capacity, quality of life and reduces hospitalization and mortality rates in these patients (Keteyian et al., 2012; O'Connor et al., 2009). However, despite all the scientific evidence and clinical recommendations, CR is underused in the treatment of HF (Humphrey, Guazzi, & Niebauer, 2014). It is estimated that in Europe only 20% of individuals with HF have access to a CR program (Bjarnason-Wehrens et al., 2010). In Portugal, HF is responsible for around 14.5% of admissions to CR programs (Fontes, Vilela, Durazzo, & Teixeira, 2021).

The reasons for the underutilization of CR programs are multifactorial and encompass healthcare system-, health professional-, or patient-level barriers (Sérvio et al., 2019). General barriers reported by patients were geographic location, transportation, financial factors, difficulties in reconciling the program with work, and bad weather (Grace, Gravely-Witte, et al., 2008; Sérvio et al., 2019; Taylor, Wilson, & Sharp, 2011). Home-based interventions have been suggested as a potential solution to overcome some of these barriers. Home-based CR have been shown to be equally effective with the clinic-based CR (Winnige, Vysoky, Dosbaba, & Batalik, 2021) and have the ability to adjust to individual needs and preferences (Anderson et al., 2017) thus increasing CR engagement and adherence and reducing dropout rates (Beckie, 2019). In other words, because it is performed at home, home-based CR may be an alternative to improve CR accessibility and patient´s adherence.

The heterogeneity of the populations and exercise prescriptions previously studied limits the external validity of available evidence to our national context. Contextual differences such as the type of health system organization and reimbursement policies, and patient characteristics and literacy may significantly influence patients-related barriers. Considering the importance of CR programs in the treatment of patients with HF, the low accessibility and adherence to this type of program, it is important to identify the reasons for this underutilization to improve the quality of services provided and support policy decisions in Portugal.

Therefore, this study aimed: i) to describe and compare barriers to adherence in a clinic versus home-based CR program in HF patients in a tertiary hospital in Portugal, and ii) to investigate whether these barriers are related to CR program adherence.

METHODS

Study design and population

The present study is a cross-sectional study from the Exercise Intervention in Heart Failure (EXIT-HF) trial (ClinicalTrials.gov Identifier: NCT04334603) with HF patients who were randomized to a clinic or home-based CR program. The study was conducted at the Cardiac Rehabilitation Unit of a tertiary hospital (*Centro Hospitalar Universitário do Porto*) between January 2020 to January 2022. The study was approved by the local research Ethics Committees (103-DEFI/107-CE). Participants provided written informed consent and all procedures followed the Declaration of Helsinki.

Eligibility criteria for the EXIT-HF study were: i) age ≥18 years old; ii) diagnosis of HF with reduced (HFrEF) or preserved ejection fraction (HFpEF) according to criteria of the European Society of Cardiology (ESC) (McDonagh Ta Fau - Metra et al., 2021); iii) clinically stable for ≥6 weeks; iv) optimal medical treatment ≥6 weeks; v) able to understand and follow the exercise prescription; and vi) sign informed consent. Exclusion criteria include: i) patients who have participated in a CR program in the last 12 months; ii) patients who received an intracardiac defibrillator (ICD), cardiac resynchronization therapy (CRT) or combined CRT/ICD device implanted in the last 6 weeks; iii) inability to exercise or any condition that may interfere with exercise intervention; iv) signs of ischemia during cardiopulmonary exercise test; v) comorbidities that may influence one-year prognosis; vi) symptomatic and/or exercise-induced cardiac arrhythmias or conduction disturbances; vii) currently pregnancy or intend to become pregnant in the next year; viii) expectation of receiving a cardiac transplant in the next 6 months; ix) participation in another clinical trial; x) patients who are unable to understand the study information or unable to complete the outcome questionnaires; and, xi) with no possibility of telephone contact.

Interventions

Patients were randomized to one of two groups: clinic-based or home-based CR program. All patients participated in 12-week combined exercise program with 2 training sessions per week, for a total of 24 sessions. Those allocate to the home-based program underwent to 4 to 5 supervised exercise training sessions (equal to those in the standard program) in the CR Unit to familiarize themselves with the training protocol and learn to use wearable device (heart rate monitor). In both groups, exercise training protocol consisted in 5-10 minutes of warm-up, 25 minutes of resistance exercises using elastic bands with 2 sets of 12-15 repetitions of each exercise (squat, leg curl, leg abduction, leg adduction, standing calf raise, bench press sitting, seated row, biceps, triceps, lateral raises), 30 minutes of moderate to vigorous aerobic training at 60%-80% of VO2peak (11-14 Borg´s scale) and 5 minutes of cool down with stretch exercises. Exercise sessions were monitoring with real-time ECG and heart rate monitor at the supervised training sessions, and by activity logs, telephone, and heart rate monitoring (model M200, Polar USA Inc) for the home-based group. The staff were supervising patient´s home-based sessions through a weekly phone call. In both groups, patients were encouraged to walk at home at least a third time, a minimum of 30 minutes.

Adherence to CR program

Adherence were evaluated by measuring sessions attendance. The exercise sessions attendance was register in a training log sheet and confirmed at the heart rate monitoring registers for home-based group. Adherence to CR was defined as to complete a minimum of 80% of prescribed sessions.

Physical activity levels

To assess physical activity levels, the short version of the International Physical Activity Questionnaire (IPAQ-SF) (Craig et al., 2003) was used. The questionnaire has 7 questions related to time and frequency spend in walking time, moderate activities, vigorous activities, and time siting in the last 7 days. The final score was computed as min/week in each physical activity intensity (Committee, 2005).

Data collection

Socio-demographic characteristics (age, gender, marital status, and educational level), clinical characteristics (etiology, left ventricular ejection fraction, New York Heart Association functional class, comorbidities, medication) were extracted from the patients' clinical file. Anthropometric (body weight, height, and waist circumference) were measured before and after the intervention.

Cardiac rehabilitation barriers were evaluated in the end of the CR program. The CR Barriers Scale (CRBS) questionnaire was applied by the researcher. This instrument assesses the patient's perception of the degree to which different barriers (healthcare system-, health professional-, or patient-level barriers) affect their participation in a CR program (Ghisi, Santos, et al., 2012; S. Shanmugasegaram et al., 2012). The questionnaire consists of 21 questions scored between 1=strongly disagree to 5=strongly agree. A higher score indicates greater barriers to the CR program, as applicable. The questions are divided in five subscales, such as comorbidities/functional status, the perceived need, personal/family issues, travel/work conflicts and assess (Ghisi, Santos, et al., 2012). In addition, open responses were allowed.

STATISTICAL ANALYSES

For data analysis, the statistical program Statical Package for the Social Sciences (SPSS) version 26.0 was used. Descriptive data are presented as absolute values and percentages, mean and standard deviation or median and interquartile ranges as appropriate.

The normal distribution of data was examined by the Shapiro-Wilk test or by the absolute values of skewness and kurtosis. Normal data were compared using Student's t test and non-normal data were compared using the Mann-Whitney test. Nominal categorical variables were analyzed using the chi-square test. The correlation between the quantitative and/or ordinal variables was verified using the Spearman’s test. Binary regression analysis was used to evaluate the association between the CR barrier score and the non-adherence of the CR program. Regression analysis results are reported as odds ratio (OR) and 95% confidence intervals (CI). For binary regression, two age groups (0= up to 65 years and 1 >65 years) and two physical activity levels groups (IPAQ min/week after CR) was created (0= <150min/week and 1= >150min/week). A two-sided p-value < 0.05 was considered as indicating statistical significance.

RESULTS

Patient's characteristics

The clinical and sociodemographic characteristics of HF patients are displayed in Table 1. They were predominantly male (72.4%) and had a mean age of 62±12 years old. Most of them were in functional class NHYA II (67.8%), had a non-ischemic etiology (55.2%) and a reduced ejection fraction (85.1%). The mean ejection fraction was 36±11 and NTproBNP levels were 793±1005 pg/mL.

Table 1: Characterization clinical and sociodemographic of the participants.

	All (n=87)	**Clinic-based (n=33)**	**Home-based (n=54)**	***p value***
Sociodemographic characteristics				
Age (years)	62±12	64±11	61±12	*p=0.220*
Male n(%)	63(72.4)	24(72.7)	39(72.2)	*p=0.959*
***Marital Status* n(%)**				
Married	64(75.3)	26(81.3)	38(71.7)	*p=0.291*
Single	9(10.6)	1(3.1)	8(15.1)	
Divorced	5(5.9)	3(9.4)	2(3.8)	
Widower	7(8.2)	2(6.3)	5(9.4)	
Missing	2(2.)	1(3.0)	1(1.9)	
***Education levels* n(%)**				
Illiterate	1(1.2)	1(3.1)	0	*p=0.072*
Elementary school	34(39.5)	16(50.0)	18(33.3)	
Middle school	34(39.5)	9(28.1)	25(46.3)	
High school	12(14.0)	6(18.8)	6(11.1)	
University	5(5.8)	0	5(9.3)	
Missing	1(1.1)	1(3.0)	0	
Anthropometrics				
Weight (kg)	77±16	74±12	80±18	*p=0.113*
Waist circumference (cm)	99±12	98±9	100±13	*p=0.415*
BMI (Kg/m^2)	28±5	28±4	28±5	*p=0.901*
Risk factors n(%)				
Hypertension	54(62.1)	24(72.7)	30(55.6)	*p=0.109*

Dyslipidemia	54(62.1)	22(66.7)	32(59.3)	*p=0.490*
Type 2 Diabetes	34(39.1)	13(39.4)	22(40.8)	*p=0.865*
Active smoker	16(18.6)	7(21.9)	9(16.7)	*p=0.650*
Obesity	25(28.7)	9(27.3)	16(29.6)	*p=0.863*
Coronary artery disease	32(36.8)	16(48.5)	16(29.6)	*p=0.077*
Atrial fibrillation	19(21.8)	8(24.2)	11(20.4)	*p=0.671*
Clinical signs				
Resting HR (bpm)	72±13	70±14	73±12	*p=0.406*
SBP (mmHg)	129±21	133±22	127±21	*p=0.181*
NTproBNP	793±1005	753±763	818±1136	*p=0.772*
LVEF (%)	36±11	36±10	37±12	*p=0.738*
LVEF Classification n(%)				
Reduced	74(85.1)	29(87.9)	45(83.3)	*p=0.529*
Preserved	7(8.0)	3(9.1)	4(7.4)	
Recovered	6(6.9)	1(3.0)	5(9.3)	
NYHA (n, %)				
Class I	22(25.3)	1(15.2)	17(31.5)	*p=0.089*
Class II	59(67.8)	27(81.8)	32(59.3)	
Class III	6(6.9)	1(3.0)	5(9.3)	
Etiology (n, %)				
Non-ischemic	48(55.2)	14(42.4)	34(63.0)	*p=0.210*
Ischemic	36(41.4)	18(54.5)	18(33.3)	
Indetermined	2(2.3)	1(3.0)	1(1.9)	
Medication, n(%)				
β-Blocker	83(95.4)	33(100.0)	50(92.6)	*p=0.109*
AAS	35(40.2)	15(45.5)	20(37.0)	*p=0.437*
ACE-i/ARB	39(44.8)	16(48.5)	23(42.6)	*p=0.592*
Statin	68(78.2)	27(81.8)	41(75.9)	*p=0.519*
Dapagliflozin	46(52.9)	21(63.6)	25(46.3)	*p=0.116*
Sacubitril/Valsartan	37(42.5)	14(42.4)	23(42.6)	*p=0.988*
Spironolactone	68(78.2)	26(78.8)	42(77.8)	*p=0.912*
ICD	13(14.9)	9(27.3)	4(7.4) *	***p=0.012***
CRT	10(11.5)	4(12.1)	6(11.1)	*p=0.886*

BMI: body mass index; HR: heart rate; SBP: systolic blood pressure; LVEF: left ventricular ejection fraction; NYHA: New York Heart Association; AAS: acetylsalicylic acid; ACE-i/ARB: angiotensin-converting-enzyme inhibitor and an angiotensin II receptor blocker; ICD: Implantable cardioverter-defibrillator; CRT: cardiac resynchronization therapy. Data are means±SD or absolute values and percentages. *p<0.05.

Cardiac rehabilitation barriers

Table 2 displays the CR barriers in descending order. Overall, the highest score barriers were “other health problems”, reported by 48.2% of patients, and “I don't have energy”, reported by 32.1% of patients. Both groups reported “other health problems” as the main barrier. The most common health problems related were musculoskeletal pain, Covid-19 complications, respiratory problems, cardiac arrhythmia, dizziness, herniated disc, anxiety, and hemorrhoids. The home-based group total score was higher than the clinic-based group (29±7 vs 26±6 points; p=0.041). More specifically, home-based CR participants rated two mains' barriers significantly higher, such as “bad weather” (2.07±1.65vs 1.06±0.24 points; p=0.002) and “I have little time” (1.59±1.37 vs 1.09±0.52 points; p=0.002). Gender comparison showed that women reported a significant higher total barriers score (p=0.002), independently of type of CR program.

Table 2: Barriers to adherence CR of the participants by questions.

Barriers	**All (n=87)**	**Clinic-based (n=33)**	**Home-based (n=54)**	***p* value**
Total Score	28±7	26±6	29±7*	***p=0.041***
Other health problems [14]	2.82±1.94	2.94±2.03	2.74±1.91	*p=0.616*
I don't have energy [13]	2.05±1.63	1.64±1.39	2.30±1.73	*p=0.078*
I find exercise tiring or painful [9]	1.72±1.45	1.39±1.17	1.93±1.58	*p=0.071*
Bad weather [8]	1.69±1.39	1.06±0.24	2.07±1.65*	***p=0.002***
Family responsibilities [4]	1.57±1.33	1.55±1.35	1.59±1.34	*p=0.739*
Cost (fuel, bus tickets) [2]	1.46±1.19	1.36±1.17	1.52±1.21	*p=0.290*
I have little time [11]	1.40±1.15	1.09±0.52	1.59±1.37*	***p=0.034***
Distance the program [1]	1.38±1.10	1.24±0.97	1.46±1.18	*p=0.242*
Job responsibilities [12]	1.34±1.10	1.12±0.70	1.48±1.27	*p=0.127*
Travel (vacation or work) [10]	1.24±0.94	1.39±1.17	1.15±0.76	*p=0.140*
Transport problems [3]	1.17±0.80	1.24±0.97	1.13±0.67	*p=0.596*
I am too old [15]	1.07±0.45	1.15±0.71	1.02±0.14	*p=0.293*
Doctor did not recommend [16]	1.07±0.45	1.15±0.71	1.02±0.14	*p=0.293*
I didn't know about CR [5]	1.05±0.43	1.00±0.00	1.07±0.54	*p=0.434*

People with heart problems do not attend CR, and they are fine [17]	1.02±0.15	1.03±0.17	1.02±0.14	*p=0.723*
I can control my heart problem [18]	1.02±0.15	1.03±0.17	1.02±0.14	*p=0.723*
Program not contacted [19]	1.02±0.15	1.03±0.17	1.02±0.14	*p=0.723*
I don't need CR [6]	1.00±0.00	1.00±0.00	1.00±0.00	*p=1.000*
I exercise in my region [7]	1.00±0.00	1.00±0.00	1.00±0.00	*p=1.000*
It took too long to get referred into the program [20]	1.00±0.00	1.00±0.00	1.00±0.00	*p=1.000*
I prefer to take care of my health alone, not in group [21]	1.00±0.00	1.00±0.00	1.00±0.00	*p=1.000*

Data are mean±SD. p<0.05.

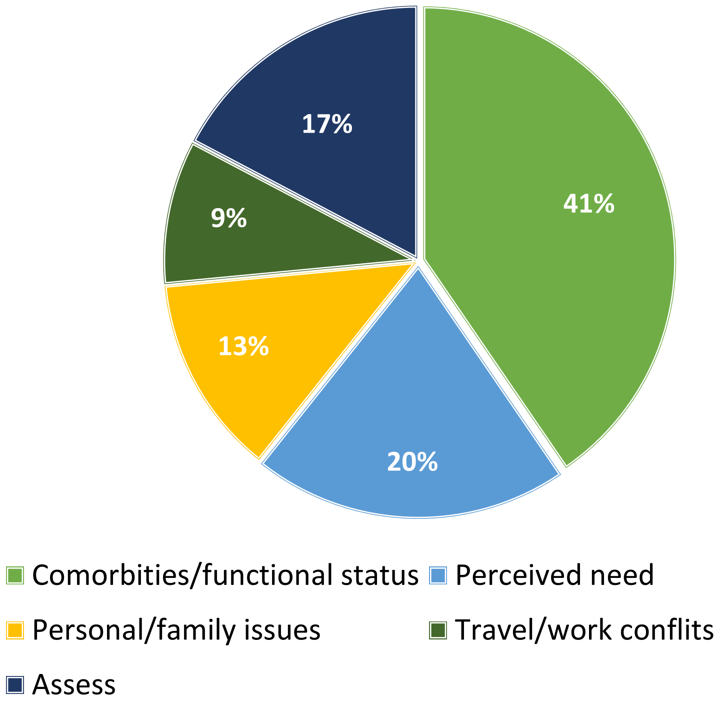

Figure 1. Participants' total score barriers to CR by subscale.

Cardiac rehabilitation barriers and program adherence

The mean CR sessions attendance was 19.5±5.8 sessions for the clinic-based CR group and 20.7±5.6 sessions for the home-based group. The number of sessions attended was significantly and negatively related to total barriers among clinic-based participants (r= -0.368; p=0.035), but not among home-based participants (r= -0.180; p=0.194). When comparing attended versus non-attended patients, there were no differences in barriers score in clinic-based group (Figure 2). On the other hand, patients that do not attended at least to 80% of prescribed sessions in the home-based group reported significant high barriers (33±7 vs. 28±7points, p=0.022). The main causes of non-adherence in both groups were “other health problem” (clinic-based = 66.7% vs home-based = 80%) and “feel that don't have energy to exercise” (clinic-based = 66.7% vs home-based = 70%).

Transport problems was significantly correlated with low attendance among clinic-based CR participants (r=-0.351; p=0.045), and the feeling of do not have energy was significantly correlated with low attendance among home-based group (r=-0.402; p=0.003).

Binary regression analysis

The CR barrier score was independently associated with non-adherence of the CR program (OR = 0.888; CI 95% = 0.803-0.982, p = 0.021), when controlled by group, age, and physical activity levels. The higher the score of the barriers, the lower the odds of the participant having adhered to the CR program.

Table 3: Binary regression with Barriers to CR and adherence of the CR program.

	OR	**95% CI**	*Sig*
Score Barriers	0.888	(0.803-0.982)	**0.021**
Group	0.146	(0.013-1.659	0.121
Physical Activity post CR (IPAQmin/week)	1.006	(0.995-1.017)	0.268
Age (group age)	0.985	(0.162-5.973)	0.987

OR= odds ratio; CI= confidence intervals.

DISCUSSION

Our study investigated the barriers to participation in a clinic- versus home-based CR program in HF patients in a tertiary hospital in Portugal. Our data demonstrated that “other health problems” was the most common barrier to CR reported by nearly 50% of HF patients regardless of the context in which the CR program was performed. Indeed, health problems related by patients, such as musculoskeletal limitations, respiratory problems, cardiac arrhythmia, and dizziness, are limiting factors for exercise training. These limitations are common in individuals with HF, suggesting the need of optimized the disease treatment and appropriately address the musculoskeletal limitations before starting the CR program.

It is already known that women are less likely to participate in CR programs than men (Khadanga, Gaalema De Fau - Savage, Savage P Fau - Ades, & Ades, 2021; Sawan, Calhoun, Fatade, & Wenger, 2022). In our study, only 28% of patients were women. Although women are less representative in CR programs, there are few studies comparing gender differences regarding CR barriers, and data from literature are still controverse (Sawan et al., 2022; Smith, Thomas, Bonikowske, Hammer, & Olson, 2022). In our study we found that when comparing the total scores of barriers, women had a significantly higher total score regardless of the group. Similar results were showed by (Rangel-Cubillos et al., 2022), who demonstrated a trend towards higher barriers scores in women than men in a Latin America population. On the other hand, (Grace et al., 2009) did not find significant gender difference in total number of CR barrier. However, Grace and collaborators showed that there were significant differences in individual barrier items by gender (Grace, Gravely-Witte S Fau - Brual, et al., 2008). Men CR participants were significantly more likely to rate work responsibilities as a barrier than women. On the other hand, women were significantly more likely to rate the tiring or painful nature of exercise as a barrier than males.

Considering the comparison of barriers to CR between the groups, the home-based group had a higher total score, and had two main barriers that were significantly higher compared to the clinic-based group, such as “bad weather” and “I have little time”. Indeed, in our study, more than 90% of the patients randomized to the home-based program performed aerobic exercise training outdoor (e.g., walking in the street), where the prevailing weather conditions may influence the success patients' use of these programs. To try to overcome this barrier, during the weekly phone call we gave them some alternatives, such as using the parking lots of supermarkets or shopping centers to perform the aerobic training. Regarding the second most reported barriers, "I have little time", some patients reported that after a full day of work, when they got home, they were tired or had personal tasks. Although home-based CR programs can be used any time and give flexibility to patients to engage on their own time and bypasses driving distance, travel costs, time away from work, or childcare obligations(Chindhy, Taub, Lavie, & Shen, 2020), our results suggested that do not have a scheduled training time and the commitment to be present at a face-to-face session may be a problem for some patients. It is important to mentioning the fact that the patients could not choose which group to participate in, may have interfered the barriers reported. Indeed, recent studies have being showed that using a patient-centered approach to program model allocation may serve to promote CR adherence (Anderson et al., 2017; Shamila Shanmugasegaram, Oh, Reid, McCumber, & Grace, 2013).

Regarding to CRBS subscales, we found that comorbidities/functional status was the most important subscale of barriers (60.7%). Similar results were demonstrated by (Ghisi, Santos Rz Fau - Schveitzer, et al., 2012). Indeed, HF incidence and prevalence increase with age, and as a result, the risk of accumulate multiple comorbidities (van der Wal, van Deursen, van der Meer, & Voors, 2017). Once again, highlight the need of an adequate screen and optimization of the treatment of comorbidities before patients starts the CR program.

The home-based CR program was expected to increase adherence. However, our data showed similar values in both groups, with 91% adherence in the clinic-based group and 82% adherence in the home-based group. This high adherence rate can be related with employee status, once that 75% of patients were not working [sick leave (13,8%), unemployed (2,3%) or retired (58,6%)] with more time availability.

Among patients that do not attend in at least 80% in the home-based group, the main barriers reported were "other health problem" and "feel that they did not have the energy” to exercise. When compared to non-adherent patients at clinic-based group, the home-based group had a superior total score of barriers. Even though home-based programs have emerged as a strategy to improve potential barriers to CR adherence (Winnige et al., 2021), they seem to also present their specific obstacles to patient’s participation in our setting. Despite that, our sample had a higher adherence rate, where 82% of patients of home-based participants complete at least 80% of prescribed sessions, with a drop-out rate around 19%. Similar results were reported in the last survey of traditional CR programs in Portugal which showed a drop-out rate bellow 25% (Fontes et al., 2021).

LIMITATIONS

Caution is need when interpreting these results due to some study limitations. The generalizability of the findings is limited by sample selection, the small sample size and the small sample of clinic-based participants comparing to home-based participants. In this sense, it is necessary caution for extrapolations results. Muti-center studies with a larger sample size are needed to identify the main barriers to CR in the Portuguese population to target strategies to improve HF patient’s adherence to CR programs.

CONCLUSIONS

Our data suggested that “other health problems” are the main limiting barrier to CR in HF patients regardless of the context in which the CR program was performed, highlighting the need for early recognition and treatment of concomitant medical problems. In addition, it seems that individualized CR programs that incorporates patient’s specific barriers will likely have a significant impact on CR participation as barriers.

Supplement material

Table 1: Barriers to CR adherence of the participants by questions and group.

	Clinic-based			Home-based		
	Adherence **(n=30)**	Non-adherence **(n=3)**	*p- value*	Adherence **(n=44)**	Non-adherence **(n=10)**	*p- value*
Total Score	25±4	36±15	*p=0.168*	28±7	33±7	***p=0.022***
Distance the program [1]	1.13±0.73	2.33±2.31	*p=0416*	1.48±1.17	1.40±1.26	*p=0.692*
Cost (fuel, bus tickets) [2]	1.27±1.01	2.33±2.31	*p=0.491*	1.45±1.09	1.80±1.69	*p=0.742*
Transport problems [3]	1.13±0.73	2.33±2.31	*p=0.416*	1.07±0.45	1.40±1.26	*p=0.234*
Family responsibilities [4]	1.47±1.25	2.33±2.31	*p=0.571*	1.45±1.23	2.20±1.69	*p=0.065*
I didn't know about CR [5]	1.00±0.00	1.00±0.00	*p=1.000*	1.09±0.60	1.00±0.00	*p=0.634*
I don't need CR [6]	1.00±0.00	1.00±0.00	*p=1.000*	1.00±0.00	1.00±0.00	*p=1.000*
I exercise in my region [7]	1.00±0.00	1.00±0.00	*p=1.000*	1.00±0.00	1.00±0.00	*p=1.000*
Bad weather [8]	1.07±0.25	1.00±0.00	*p=0.883*	2.16±1.68	1.70±1.49	*p=0.350*
I find exercise tiring or painful [9]	1.30±1.02	2.33±2.31	*p=0.531*	1.86±1.50	2.20±1.93	*p=0.750*
Travel (vacation or work) [10]	1.43±1.22	1.00±0.00	*p=0.745*	1.18±0.84	1.00±0.00	*p=0.496*
I have little time [11]	1.10±0.55	1.00±0.00	*p=0.930*	1.55±1.30	1.80±1.69	*p=0.818*
Job responsibilities [12]	1.13±0.73	1.00±0.00	*p=0.930*	1.41±1.17	1.80±1.69	*p=0.423*
I don't have energy [13]	1.43±1.14	3.67±2.31	*p=0.115*	1.98±1.55	3.70±1.89	***p=0.007***
Other health problems [14]	2.87±2.03	3.67±2.31	*p=0.614*	2.41±1.81	4.20±1.69	***p=0.006***
I am too old [15]	1.03±0.18	2.33±2.31	*p=0.416*	1.02±0.15	1.00±0.00	*p=0.634*

Doctor did not recommend [16]	1.03±0.18	2.33±2.31	*p=0.416*	1.02±0.15	1.00±0.00	*p=0.634*
People with heart problems do not attend CR, and they are fine [17]	1.03±0.18	1.00±0.00	*p=0.930*	1.02±0.15	1.00±0.00	*p=0.634*
I can control my heart problem [18]	1.03±0.18	1.00±0.00	*p=0.930*	1.02±0.15	1.00±0.00	*p=0.634*
Program not contacted [19]	1.03±0.18	1.00±0.00	*p=0.930*	1.02±0.15	1.00±0.00	*p=0.634*
It took too long to get referred into the program [20]	1.00±0.00	1.00±0.00	*p=1.000*	1.00±0.00	1.00±0.00	*p=1.000*
I prefer to take care of my health alone, not in group [21]	1.00±0.00	1.00±0.00	*p=1.000*	1.00±0.00	1.00±0.00	*p=1.000*

BMI: body mass index; HR: heart rate; SBP: systolic blood pressure; LVEF: left ventricular ejection fraction; NYHA: New York Heart Association; AAS: Acetylsalicylic acid; ACE-i/ARB: angiotensin-converting-enzyme inhibitor and an angiotensin II receptor blocker; ICD: Implantable cardioverter-defibrillator; CRT: Cardiac resynchronization therapy. Data are mean ± SD or absolute values and percentages.

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STUDY II

LONG-TERM EFFECTS OF HOME-BASED VERSUS CLINIC-BASED CARDIAC REHABILITATION IN PATIENTS WITH HEART FAILURE

ABSTRACT

Introduction: Exercise-based cardiac rehabilitation (CR) is an essential therapy for patients with heart failure (HF). Following program completion, most patients fail to maintain the exercise training routine and return to a sedentary lifestyle. Therefore, it is important to find strategies capable to enhance long-term adherence.

Aims: Therefore, the aim of this study was to verify the effectiveness of home-based CR (HBCR) program on short- (12-weeks) and long term (12 months) physical activity (PA) adherence and physical fitness after phase II CR in HF patients, and to compare HBCR vs clinical-based (CBCR) intervention.

Methods: We evaluated HF patients who were followed for 1-year after either HBCR or CBCR program by assessment of PA levels and physical fitness, both at the completion of CR program (12 weeks), and after 1-year. PA was assessed through the International Physical Activity Questionnaire and by the POLAR M200. Physical fitness was assessed through the 6-minute-walking test (6MWT), the 8-foot-up-and go test, handgrip, and the 30-second sit to stand test.

Results: Fifty-four patients (CBCR: 17; HBCR: 37) with a mean age of 63±10 years old completed the assessments. PA levels increased after CR in both groups, but it was significant only for the HBCR group (+125min/week IQR:70;205, $p=0.045$). The percent of patients how met international PA guidelines increased to 82% in the CBCR and 73% in the HBCR ($p<0.05$). After 1-year, total PA levels decreased (CBCR: -60min/week, IQ: -240;63, $p=0.589$; HBCR: -120min/week, IQR: -310; -10, $p<0.001$), and patients who met the PA guidelines targets decreased by 41% in the CBCR group ($p=0.039$) and 27% in the HBCR group ($p=0.035$). Physical fitness improved in both groups after CR with an increase in the 6MWT (CBCR: +51 meters, 95%CI:23 to 79, $p<0.001$; HBCR: +48 meters, 95%CI:35 to 61, $p<0.001$) and with improvements in lower limb strength and dynamic balance/mobility ($p<0.05$) but returned to baseline levels after 1-year of follow up.

Conclusions: HBCR did not results in a better long-term PA adherence or physical fitness levels comparing with the CBCR intervention. This suggests that a 12-week home-based CR program is not enough to promote a favorable transition to sustainable behavioral change over time.

Keywords: cardiac rehabilitation, long-term effects, adherence, home-based, heart failure.

INTRODUCTION

Cardiovascular diseases (CVD) are the leading cause of death worldwide and its prevalence almost doubled in recent decades, rising from 271 million to 523 million (Roth et al., 2020). The epidemiological picture of CVD has changed, with an increase in diseases such as heart failure (HF) being observed (Emmons-Bell, Johnson, & Roth, 2022). The increased number of people living with HF may be associated with the aging of the population, global population growth and improved survival (Groenewegen, Rutten, Mosterd, & Hoes, 2020).

Heart failure remains a major clinical and public health problem which affect more than 26 million people worldwide (Fonseca, Brás, Araújo, & Ceia, 2018). In Portugal, the burden of HF is expected to increase by 28% and mortality by 73% until 2036 due to population aging (Gouveia et al., 2019). Despite a variety of pharmacological and device therapies for HF, patients still have a poor long-term prognosis and quality of life (Packer & Metra, 2020).

Exercise-based cardiac rehabilitation (CR) has been considered an essential component in treatment of these patients (McDonagh Ta Fau – Metra et al., 2021) since it improves patients´ quality of life, functional capacity and reducing the risk of hospitalization and mortality (Y. M. Chen & Li, 2013; Keteyian et al., 2012). Following program completion, patients are encouraged to maintain the exercise training routine on their one to preserve the achieved health benefits.

However, most patients fail to maintain the exercise training (ExT) routine and return to a sedentary lifestyle. Data from the literature show that less than 50% of patients continue exercising on their own after CR completion (Hansen et al., 2010). Poor adherence to ExT results in reversion of the obtained benefits (Giallauria et al., 2006; Hansen et al., 2010; Volaklis, Douda, Kokkinos, & Tokmakidis, 2006) and limits the potential of CR to change the patient prognosis. Failure to maintain or increase post-CR physical activity (PA) levels may be attributed to multiple factors including lack of time and motivation, loss of social support and low self-efficacy (Fletcher et al., 2018; Hately & Mandic, 2019; Mandic et al., 2015).

Home-based interventions, either alone or in combination with clinic-based CR have the potential to address some of these problems. The European Guidelines on Cardiovascular Diseases Prevention highlight that home-based programs with and without telemonitoring is a promising strategy to increase CR participation and supporting behavioral change (McDonagh Ta Fau - Metra et al., 2021). The higher degree of self-monitoring/management required in home-based programs, may promote a favorable transition to sustainable behavioral change and disease self-management. The potential of home-base CR to preserve and/or improve the achieved health benefits after a phase II CR programs in HF patients have been study in other countries (Cowie, Thow, Granat, & Mitchell, 2011). Nevertheless, the diverse nature of the populations under study restricts the generalizability of the existing evidence to our specific national setting. Therefore, the aim of this study was to verify the effectiveness of home-based CR (HBCR) program on PA adherence and physical fitness after phase II CR in HF patients, and to compare home-based vs clinic-based CR (CBCR) intervention in a public hospital in Portugal. Our hypothesis is that HBCR would increase long-term PA adherence and would maintain or improve physical fitness levels.

METHODS

Study design

We performed a prospective cohort study at the Cardiac Rehabilitation Unit of the *Centro Hospitalar Universitário do Porto* (CHUP). All subjects provided informed consent before enrolment in the study. The study protocol was approved by the local Research Ethics Committee of the CHUP in accordance with Portuguese Law (DL nº 97/94 of April 9, 1994) under number 2019.123 (103-DEFI/107-CE).

Population

We included patients for the EXIT-HF study were: i) age ≥18 years old; ii) diagnosis of HF with reduced (HFrEF) or preserved ejection fraction (HFpEF) according to criteria of the European Society of Cardiology (ESC) ((Ponikowski et al., 2016; McDonagh Ta Fau - Metra et al., 2021); iii) clinically stable for ≥6 weeks; iv) optimal medical treatment ≥6 weeks; v) able to understand and follow the exercise prescription; and vi) sign informed consent that completed both home-based (HBCR) and clinic-based CR (CBCR). Exclusion criteria include: i) patients who have participated in a CR program in the last 12 months; ii) patients who received an intracardiac defibrillator (ICD), cardiac resynchronization therapy (CRT) or combined CRT/ICD device implanted in the last 6 weeks; iii) inability to exercise or any condition that may interfere with exercise intervention; iv) signs of ischemia during cardiopulmonary exercise test; v) comorbidities that may influence one-year prognosis; vi) symptomatic and/or exercise-induced cardiac arrhythmias or conduction disturbances; vii) currently pregnancy or intend to become pregnant in the next year; viii) expectation of receiving a cardiac transplant in the next 6 months; ix) participation in another clinical trial; x) patients who are unable to understand the study information or unable to complete the outcome questionnaires; and, xi) with no possibility of telephone contact The study was conducted between September 2019 and December 2022.

Interventions

In both groups' patients participate in a 12-week combined ExT program with 2 training sessions per week, for a total of 24 sessions. ExT protocol consists of 5-10 minutes of warm-up with calisthenic and stretching exercise, 25 minutes of resistance exercises using elastic bands with 2 sets of 12-15 repetitions of ten exercises (squat, leg curl, leg abduction, leg adduction, standing calf raise, bench press sitting, seated row, biceps, triceps, lateral raises), 30 minutes of moderate to vigorous aerobic training corresponding to 60%-80% heart rate at VO2peak (11-14 Borg´s scale), and 5 minutes of cool down with stretch exercises. In both groups, patients are encouraged to walk at home at least a third time, a minimum of 30 minutes.

Clinic-based group

The clinic-based group received a CR program at the hospital, which includes 24 supervised ExT sessions and counselling for lifestyle modification. Exercise training was monitored with real-time ECG and heart rate monitor (model Polar M200; Polar Electro Ltd). During aerobic training, the speed and inclination of the treadmill were adjusted to ensure that every training session were carried out at the assigned heart rate level. The resistance training intensity were progressively increased according to rated perceived exertion scale. When patients performed the set comfortably (11-14 Borg´s scale) and would be able to perform more two repetitions than the prescribed ones, the intensity was increased. Adherence, defined as the total exercise sessions during the intervention, were evaluated by measuring sessions attendance.

Home-based group

The HBCR group participates in a technology-enabled (computer or mobile phone application linked to a wearable smartwatch) program following the same ExT prescription of the CBCR program. The HBCR program consists of unsupervised exercise sessions (walking), weekly phone calls and counselling for lifestyle modification. At the beginning of the program, those allocated to the HBCR program were underwent to 4 to 5 supervised ExT sessions (equal to those in the CBCR program) to familiarize themselves with the training protocol and learn how to use the wearable smartwatch (heart rate monitor, model Polar M200; Polar Electro Ltd.) and fill out the exercise logs. After these sessions, patients started training in their home environment. Every exercise session completed by the participant were recorded by the smartwatch and uploaded to the Polar Flow application (Polar Flow, Polar Electro Ltd.). Participants were telephoned every week to monitor progress. During phone calls, a semi-structured interview was conducted to verify adherence to the exercise prescription, to identify problems/barriers to achieving the exercise goals, to provide training-specific advice for the adaptation of the exercise program on the patient's home environment, adjust ExT intensity and accomplish the recommended prescription, and to provide counselling for lifestyle modification.

Patients were instructed to contact the rehabilitation center staff if they experience any symptoms during and after exercising. Adherence were evaluated by the smartwatch, exercise logs, and telephone.

Outcome measures

Patients were evaluated by PA and physical fitness at baseline (T1), at the completion of CR program (12 weeks; (T2)), and after 1-year (T3).

***i) Physical activity**:* To assess adherence to PA, the short version of the International Physical Activity Questionnaire (IPAQ) (Craig et al., 2003) was used. The questionnaire has 7 questions related to time and frequency spend in walking time, moderate activities, vigorous activities, and time siting in the last 7 days. The final score was computed as min/week in each physical activity intensity, and to calculate moderate-to-vigorous PA (MVPA), we merged the self-reported activities ≥3 METs Ipaq Research Committee, 2005). Adherence to PA was defined as to achieve international PA guidelines of 150 min/week of MVPA (Heidenreich et al., 2022).

Physical activity was also determined by the number of daily steps of the patients through a triaxial accelerometer copulate to the POLAR M200.

ii) Physical fitness: Physical fitness was assessed using tests that measure functional capacity, handgrip strength, lower limb strength, and dynamic balance/mobility.

For functional capacity analysis, the six-minute walk test (6MWT) (Giannitsi et al., 2019). It was performed in an indoor corridor with a course of 25 m, marked every 5 metres with cones. Baseline oxygen saturation, heart rate, brachial arterial blood pressure and the Borg scale rating will be recorded. During the test, the participants must walk as fast as they can, and they are allowed to stop or slow down if they feel like doing it. At the end of the test, the Borg scale, heart rate, number of laps and the additional distance covered were recorded.

The analysis of isometric handgrip strength was performed through the handgrip test using an isometric hand dynamometer (Lafayette Model 78010,78011, Indiana, USA) (Mendes et al., 2017). To carry out the test, patients were seated in a chair with their backs and arms supported. In addition, the elbow was flexed at 90º, with the shoulders neutral and in adduction, and the forearm in the neutral position. Both arms were measured 3 times, and the average between trials was used as the final score for each arm.

The lower limb strength was assessed by the 30-second chair stand test (Rikli & Jones, 2013). Patients were initially positioned sitting on a chair without arms and with their arms crossed in front of the chest or at the side of the body. On command, they were required to stand up and sit down quickly and as safely as possible. The number of repetitions performed in 30 seconds were registered. Dynamic balance and mobility were assessed using the 8-foot up and go test (8FUG) (Rikli & Jones, 2013). In summary, the individuals sat on a chair with arms and were instructed to stand up and walk forward up to 2.44 meters, make a turn around a cone, and return to the initial position as fast as possible. Each participant performed the test twice and the best time was used for the analyses.

STATISTICAL ANALYSES

Descriptive statistics were used to assess sociodemographic characteristics. Data are presented in frequency (%), mean (standard deviation, SD) or median (interquartile ranges, IQR) as appropriate. The normal distribution of the data was examined by the Shapiro-Wilk test or by the absolute values of skewness and kurtosis. To compare differences between groups at baseline, normal data were compared using independent sample t-test and non-normal data were compared using the Mann-Whitney test. Nominal categorical variables were analyzed using the chi-square test. To assess differences between-group and within-group outcomes at both 12 weeks and 1-year, General Linear Models with repeated measures and McNemar tests were used. Meeting international PA guidelines was defined as ≥150 minutes/week of MVPA (Physical Activity Guidelines Advisory Committee Scientific Report, 2018). A significant value of $p<0.05$ was considered. Analyzes were performed using SPSS for Windows (version 27.0).

RESULTS

Fifty-four patients (14 female, 40 male) with a mean age of 63±10 years old completed the evaluations at the three time-point. Seventeen patients took part in the CBCR group (4 female,13 male, age 64±9 years) and 37 patients in the HBCR group (10 female, 27 male, age 63±10 years). Both groups had similar characteristics at baseline. Clinical and sociodemographic characteristics of the studied population are described in Table 1.

Table 1. Baseline clinical and sociodemographic characteristics of the studied population according to participation in a cardiac rehabilitation program.

	All (n=54)	CBCR (n=17)	HBCR (n=37)	*p*-value
Sociodemographic characteristics				
Age (years)	63 (10)	64 (9)	63 (10)	0.366
Male, n (%)	40 (74.1)	13 (76.5)	27 (73.0)	0.785
BMI (Kg/m^2),	28 (5)	28 (5)	29 (5)	0.948
Education levels, n (%)				
Elementary school	24 (44.4)	7 (41.2)	17 (45.9)	0.438
Middle school	23 (42.6)	6 (35.3)	17 (45.9)	
High school	6 (11.1)	4 (23.5)	2 (5.4)	
University	1 (1.9)	0	1 (2.7)	
Risck fators, n (%)				
Hypertension	37 (68.5)	15 (88.2)	25 (67.6)	0.107
Dyslipidemia	32 (59.3)	10 (58.8)	22 (59.5)	0.965
Type 2 Diabetes	22 (40.8)	7 (41.2)	15 (40.5)	0.781
Active smoker	9 (16.7)	4 (23.5)	5 (13.5)	0.650
Obesity	18 (33.3)	5 (29.4)	13 (35.1)	0.918
Coronary artery disease	12 (22.2)	5 (29.4)	7 (18.9)	0.389
Atrial fibrillation	10 (18.5)	4 (23.5)	6 (16.2)	0.521
Sedentary lifestyle	35 (64.8)	9 (52.9)	26 (70.3)	0.216

Clinical features				
Resting HR (bpm)	72 (14)	72 (15)	71 (13)	0.918
SBP (mmHg)	130 (21)	130 (23)	129 (20)	0.881
LVEF (%)	37 (11)	38 (9)	38 (11)	0.395
LVEF Classification, n (%)				
Reduced	46 (85.2)	15 (88.2)	31 (83.8)	0.913
Preserved	1 (7.4)	1 (5.9)	3 (8.1)	
Recovered	4 (7.4)	1 (5.9)	3 (8.1)	
NYHA (n, %)				
Class I	11 (20.4)	1 (5.9)	10 (27.0)	0.265
Class II	38 (70.4)	15 (88.2)	23 (62.2)	
Class III	5 (9.3)	1 (5.9)	4 (10.8)	
Etiology (n, %)				
Non-ischemic	31 (57.4)	7 (41.2)	24 (64.9)	0.102
Ischemic	23 (42.6)	10 (58.8)	13 (35.1)	
Medication, n(%)				
β-Blocker	52 (96.3)	17 (100.0)	35 (94.6)	0.329
AAS	20 (37.0)	8 (47.1)	12 (32.4)	0.301
ACE-i/ARB	30 (55.6)	10 (58.8)	20 (54.1)	0.743
Statin	43 (79.6)	14 (82.4)	29 (78.4)	0.736
Dapagliflozin	24 (44.4)	9 (52.9)	15 (40.5)	0.394
Sacubitril/Valsartan	20 (37.0)	6 (35.3)	14 (37.8)	0.857
Spironolactone	41 (75.9)	13 (76.5)	28 (75.7)	0.949
ICD/CRT	15 (28.8)	7 (41.2)	10 (27.0)	0.298

Data are mean±DP. CBCR: clinic-based cardiac rehabilitation; HBCR: home-based cardiac rehabilitation; BMI: body mass index; HR: heart rate; SBP: systolic blood pressure; LVEF: left ventricular ejection fraction; NYHA: New York Heart Association; AAS: accetylsalicylic acid; ACE-i/ARB: angiotensin-converting-enzyme inhibitor and an angiotensin II receptor blocker; ICD: Implantable cardioverter-defibrillator; CRT: cardiac resynchronization therapy.

Physical activity levels

Baseline PA levels are described in Table 2. Patients reported a median of 150 (7.5–300) minutes per week of total PA. Specifically, their median weekly in walking activity was 90 (0-214) minutes and 0 (0-64) minutes in moderate PA. The mean steps number was 1038±4636 steps per day. No significant differences were found between groups. At baseline, 29 patients (54%) (10 patients from CBCR group and 19 from HBCR group), accomplished the PA recommendations of MVPA.

Table 2. Characterization of baseline physical activity and physical fitness levels.

	All (n=54)	**CBCR (n=17)**	**HBCR (n= 37)**	***p***
Physical activity				
IPAQ (min/wk), median (IQR)	150 (7.5-300)	150 (40-290)	150 (10-300)	0.836
IPAQ MOD (min/wk), median (IQR)	0 (0-64)	0 (0-60)	0 (0-60)	0.839
IPAQ walk (min/wk), median (IQR)	90 (0-214)	120 (0-210)	90 (0-225)	0.977
Daily steps (n), mean (SD)	10038 (4636)	9883 (3008)	10073 (5368)	0.842
Adherence to physical activity				
IPAQ ≥150 min/wk, n (%)	29 (53.7)	10 (58.8)	19 (51.4)	0.609
Physical fitness				
6MWD (m), mean (SD)	452.9 (87.7)	440.7 (107.5)	458.6 (77)	0.513
Handgrip (kg), mean (SD)	30.1 (10.1)	29.5 (12.0)	30.5 (9.3)	0.751
STS-30 (n), mean (SD)	12.0 (3.4)	11.2 (3.0)	12.5 (3.5)	0.211
8FUG (sec), median (IQR)	6.2 (5.1-7.3)	6.0(5.0-7.7)	6.2 (5.2-7.2)	0.773

Abbreviation: CBCR: clinic-based cardiac rehabilitation; HBCR: home-based cardiac rehabilitation; IPAQ: international physical activity questionnaire; PA: physical activity STS-30: 30-second sit to stand test; 8FUG: 8-foot-up-and go test; 6MWD: 6-minute walking distance. IQR: interquartile range; SD: standard deviation.

The values related to PA and physical fitness variables after 12 weeks of CR program and after 1 year of follow-up are present in table 3.

Total PA levels after the CR program increased in both groups, but it was only significant for the HBCR group (+125 min/week IQR:70;205, p=0.045).

Patients how met the international PA guidelines had increased to 82% and 73% patients at CBCR and HBCR group respectively ($p<0.05$ in both groups). Daily steps had a small improvement in both groups, but it was not statistically significative. After 1-year of follow-up, total PA levels decreased (CBCR: -60 min/week, IQ: -240;63, p=0.589; HBCR: -120min/week, IQR: -310; -10, $p<0.001$), but it was statistically significant only in the HBCR group. The percent of patients how met the international PA guidelines decreased 41% in CBCR group (p=0.039) and 27% in the HBCR (p=0.035). Daily steps were significantly reduced in the HBCR group (-1405±2946, p=0.007) but not in the CBCR (-183±3750, p=0.101).

Comparing with baseline PA levels, both groups returned to initial levels of weekly PA after 1-year follow-up. Furthermore, the percent of patients how met the international PA guidelines (Figure 1) were similar to baseline ($p>0.05$).

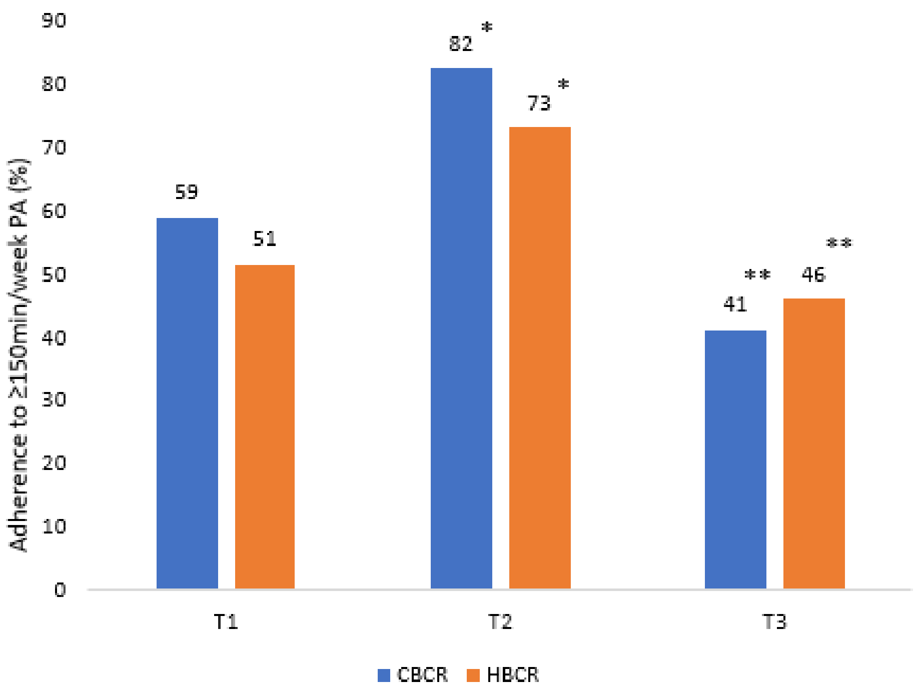

Figure 1. Adherence to international PA guidelines (IPAQ ≥150 min/week) at each moment of evaluation by group. PA: physical activity. * vs. T1. ** vs. T2.

Table 3. Values related to PA and physical fitness variables after 12 weeks of CR program and after 1 year of follow-up.

	CBCR (n = 17)						HBCR (n = 37)						Between groups p-value		
	△T2-T1	△T3-T2	△T3-T1	***p*** T2-T1	***p*** T3-T2	***p*** T3-T1	△T2-T1	△T3-T2	△T3-T1	***p*** T2-T1	***p*** T3-T2	***p*** T3-T1	***p*** △T2-T1	***p*** △T3-T2	***p*** △T3-T1
Physical activity															
Daily steps (n)*	1794 (4200)	183 (3750)	1977 (4708)	0.101	0.585	0.103	1000 (5098)	-1405 (2946)	-632 (4723)	0.370	**0.007**	0.412	0.424	0.296	0.070
IPAQ (min/wk)**	40 (-25; 225)	-60 (-250; 63)	0 (-250; 88)	0.589	0.405	0.793	125 (70- 205)	-120 (-310; -10)	0 (-100; 100)	**0.045**	**<0.001**	0.306	0.519	0.200	0.689
Physical fitness															
6MWD (m)*	54 (55)	-27 (42)	26 (44)	**<0.001**	0.157	0.363	52 (39)	-17 (59)	30 (73)	**<0.001**	0.269	0.090	0.377	0.430	0.350
Handgrip (kg)*	0.9 (3.7)	-1.2 (3.4)	-0.1 (4.8)	0.319	0.234	0.926	1.1 (4.1)	-1.1 (4.6)	0 (5.6)	0.107	0.272	0.933	0.653	0.582	0.676
STS-30 (n)*	3.8 (3.1)	-1.7(3.1)	0.1 (2.7)	**<0.001**	**0.040**	0.221	1.4 (2.8)	-0.9 (2.8)	0.4 (2.8)	**0.002**	0.327	0.134	0.364	0.412	0.935
TUG (sec)**	-0.28 (-1.8; 0.15)	0.43 (-0.13; 1.4)	-0.31 (-1.0; 0.12)	**0.015**	**0.035**	0.141	-0.60 (-1.5; -0.04)	0.71 (0.07; 1.2)	-0.36 (-0.9; 0.69)	**<0.001**	**0.005**	0.739	0.837	0.418	0.330

CBCR: clinic-based cardiac rehabilitation; HBCR: home-based cardiac rehabilitation; IPAQ: international physical activity questionnaire; PA: physical activity; 6MWD: 6-minute walking distance, STS-30: 30-second sit to stand test, 8FUG: 8-foot up and go test. *Data are mean±SD; **data are median and interquartile range.

Physical fitness

Baseline physical fitness values are described in Table 2. In the total sample, the average distance performed at the 6MWT was 453±88 meters, mean handgrip strength was 30.1±3.4 kg, the mean repetitions on the 30-second sit to stand test was 12±3.4, and the median time in the 8-foot-up-and go test was 6.2 (5.1-7.3) seconds. No significant differences were found between groups.

Functional capacity improves in both groups after CR program showed by a significant increase in the 6MWT (CBCR: +51 meters, 95%IC:23 to 79, $p<0.001$; HBCR: +48 meters, 95%IC:35 to 61, $p<0.001$) (Figure 2). Handgrip strength had no significant improvement. On the other hand, lower limb strength and dynamic balance/mobility were significant improved in both groups ($p<0.05$). There were no significant differences between groups over the time regarding physical fitness parameters.

Both groups reduced the distance performed at the 6MWT test after 12 months, but it was not statistic significantly. No difference was observed in handgrip strength. Lower limb strength was significant reduced in CBCR group (-1.7 repetitions, 95%IC:2.2 to 5.5, $p=0.04$) and dynamic balance/mobility got worse in both groups (CBCR: +0.43 seconds, 95%IC: -1.6 to 0.2, $p=0.035$; HBCR: +0.71 seconds, 95%IC: -1.2 to -0.5, $p=0.005$). There were no significant differences between groups.

Finally, both groups showed similar values in physical fitness parameters compared to the beginning of the program (baseline) after 1-year of the end of CR.

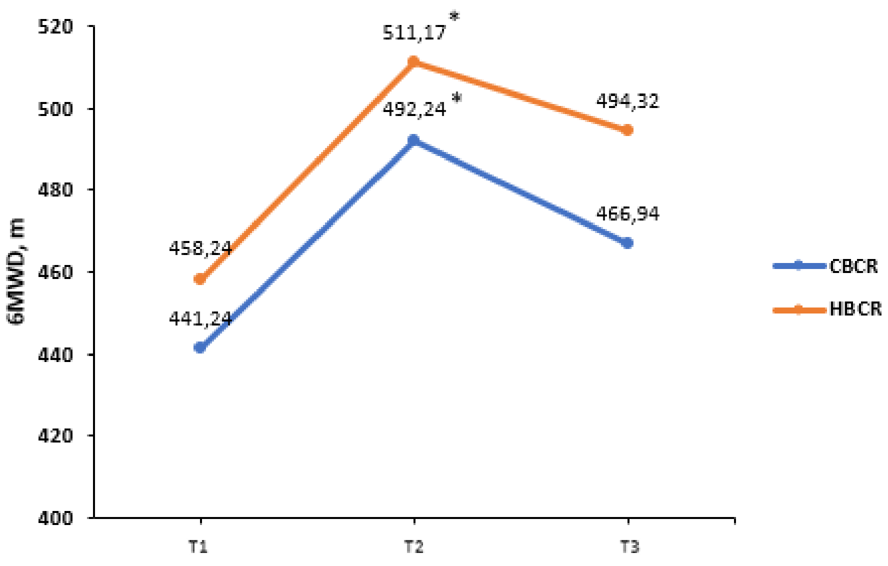

Figure 2. Changes in functional capacity after cardiac rehabilitation program and 1-year of follow-up. *within-group compression vs T1. There was no significant difference between the two groups over time. 6MWD: 6-minute walking distance.

DISCUSSION

To our knowledge this is the first study to compare the long-term effects of HBCR versus CBCR program in patients with HF in the context of Portuguese population. Contrary to our hypothesis, results showed that HBCR was not able to maintain or improve long-term PA adherence or physical fitness levels. It suggests that 12 weeks of a home-based CR program is not enough to promote a favorable transition to sustainable behavioral change.

Our results corroborate previous studies (Y. W. Chen et al., 2018; Kraal et al., 2017b; Taylor, Dalal, & McDonagh, 2022) showing that both CR programs improve the adherence to the PA recommendations (≥150 min/week of MVPA) after a 12-week program. At the end of the CR programs, 82% and 73% of patient's in CBCR and HBCR groups, respectively, were physically active. However, after 1-year of follow-up, PA levels returned to values similar to baseline, in agreement with other studies (Cowie et al., 2011; Jolly et al., 2009).

Cowie and collaborators (Cowie et al., 2011) randomized 60 HF patients to home-based training, clinic-based training, or control, and did not find significant differences in PA levels at long-term assessment. One the other hand, the study by Kraal et al. (Kraal et al., 2017b) reported that patients-maintained levels of PA acquired after three months of CR either home-based training with telemonitoring guidance or clinic-based training. This disparity in results could be attributed to differences in the characteristics of populations studied. The afore mentioned study included only low and moderate-risk patients, whereas our study also included high risk patients, who are more prone to experiencing complication during follow up. Indeed, in our study, around 15% of patients reported disease complication during follow-up period. In addition, due the selection process, Kraal´s study included mainly young patients, while in our study the mean age of patients was 63±10 years old. Furthermore, participation in Kraal´s study required patients to have Internet access and a personal computer, which implies a higher economic level compared to our studied population.

Contextual differences such as education levels, socioeconomic level and literacy may significantly influence long-term adherence to PA. The heterogeneity of the populations previously studied in different countries limits the external validity of available evidence to our national context. Recent data from our cohort population showed that patients enrolled in CR programs at CHUP hospital were more likely to have lower education levels (defined as completion of education to primary school level or below) (Alexandre et al., 2022), which could influence long-term adherence to PA.

Regarding to physical fitness, our research showed that both CR programs were able to improve different parameters, namely cardiorespiratory fitness, lower limb strength and mobility/dynamic balance. Short-term improvements on cardiorespiratory fitness are a well establish benefit reported by most of the studies (Y. W. Chen et al., 2018; Imran et al., 2019; Kraal et al., 2017a). However, in our study, after 1-year follow-up these improvements were lost regardless of the intervention group. These results contrast with a recent systematic review (Nso et al., 2022) which aimed to understand the long-term efficacy of home-based versus clinic-based CR interventions for cardiac patients. The author concluded that home-based telemedicine-oriented CR programs had the capacity to improve the long-term overall physical fitness of patients with cardiovascular diseases. However, the findings from this study were limited by its small sample size and a high risk of bias concerning allocation concealment and blinding of participants/outcome assessment.

The results observed in our study could be related with the non-monitoring after the end of CR. Data from the literature showed that a phase 3 HBCR program with telemonitoring results in an additional improvement in physical fitness (Avila et al., 2020). In addition, the study of Park et al. demonstrated a positive long-term PA adherence using an intervention of daily text messages (SMS) in combination with a supporting website (Park, Beatty, Stafford, & Whooley, 2016). Face-to-face PA counseling sessions after CR has also been demonstrated to be efficacy (ter Hoeve et al., 2018). It seems that continued patient interaction and monitoring, as well as a phase 3 CR program may be required to maintain patients motivated and active, and to obtain long-term clinic benefits.

If preference-based trial-arms was included in the study design, a more mixed population could be obtained. It is important to mention that the fact that patients cannot choose which group to participate may interfere with the barriers for long-term adherence. Recent studies have shown that employing a patient-centered approach to allocation of the program model can serve to promote long-term adherence to CR (Anderson et al., 2017; Shanmugasegaram, Oh, Reid, McCumber, & Grace, 2013). Allocate each patient according to their preference can contribute to reducing barriers, as well as increasing adherence to CR programs, in addition to enabling a more mixed population in trials.

LIMITATIONS

This study has some limitations that need to be considered. First, the CR interventions were not design specifically to the purpose of this study. This is a secondary analysis of the EXIT-HF trial. Second, the study population was derived from a single tertiary academic hospital of a universal coverage healthcare system, thereby restricting the generalizability of the findings. Third, the generalizability of the findings is also limited by sample selection and the small sample size.

CONCLUSIONS

Home-based intervention was not able to maintain and/or improve long-term PA adherence or physical fitness levels comparing with the clinic-based group. This suggests that 12 weeks of both home-based and clinic-based CR program would not be enough to promote a favorable transition to sustainable behavioral change.

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STUDY III

COMMUNITY HEART STUDY: COMMUNITY-BASED CARDIAC REHABILITATION - A PRAGMATIC NON-RANDOMIZED CONTROLLED TRIAL

ABSTRACT

Introduction: Cardiac rehabilitation (CR) is an evidence based secondary prevention intervention that reduces hospitalization and death in patients with chronic heart failure (HF) or a history of myocardial infarction (MI) or coronary revascularization. After completing the CR, patients are encouraged to maintain the exercise training (ExT) routine in order to preserve the health benefits achieved. However, the majority of patients cannot sustain the ExT routine and return to a sedentary lifestyle which could reverse the benefits obtained. Therefore, it is necessary to find strategies to overcome these limitations and provide the necessary support to help patients maintain an active lifestyle after the end of phase II CR.

Objective: This study aims to test the effectiveness of a community-based phase III CR program in achieving a sustainable healthy lifestyle, optimal management of cardiovascular (CV) risk factors, and promoting overall well-being among cardiac patients after phase II CR.

Methods: The study is a single-center, non-blinded, parallel groups, non-inferiority pragmatic non-randomized clinical trial. Participants will be allocated according to their preference for a centre-based (CBCR) or hybrid intervention (HyCR). The program will consist in 12 months of aerobic and resistance training of moderate intensity to be performed 3 times/week, 60 minutes/session. The CBCR group will perform 2 supervised sessions per week while the HyCR group will perform 4 supervised sessions at the begging of the program, and 1 supervised session every 2 months. The assessments will include cardiopulmonary exercise test, CV risk factors, physical fitness, physical activity, quality of life and psychological wellbeing which will be assessed at baseline, at 12 months. Barriers to CR will be evaluated at 12 months.

Expected results: This study is expected to have a substantial impact for the individual and the society, reducing health and economic burden, by improving CVD management through the achievement of sustainable healthy lifestyle.

Keywords: cardiac rehabilitation, cardiac patients, phase III, community.

INTRODUCTION

Cardiovascular diseases (CVD) constitute the leading cause of morbidity and premature death worldwide, accounting for over 30% of all cases and resulting in 17.9 million deaths globally (World Health, 2020). After a major cardiac event, such as myocardial infarction (MI) or coronary revascularization, the current class 1A recommendation is to refer patients to phase II cardiac rehabilitation (CR) (Visseren et al., 2021). Cardiac rehabilitation an evidence-based secondary prevention program that significantly improves patients' quality of life (QoL) while effectively mitigating the risk of heart attack, hospitalization, and mortality among individuals with history of chronic heart failure (HF), MI or coronary revascularization (Dibben et al., 2021; Long et al., 2019).

After completing the CR program, patients are encouraged to maintain the exercise training (ExT) routine in order to preserve the health benefits achieved. However, the majority of patients cannot sustain the ExT routine and return to a sedentary lifestyle. Data from the literature indicate that fewer than 50% of patients maintain regular exercise on their own after CR completion (Hansen et al., 2010). Low adherence to ExT results in reversion of achieved benefits, such as declining physical fitness and worsening of CVD risk profile and limits the potential of CR to change the patient prognosis (Giallauria et al., 2006; Hansen et al., 2010; Volaklis, Douda, Kokkinos, & Tokmakidis, 2006).

Failure to maintain or increase post-CR physical activity (PA) levels can be attributed to various factors, including lack of time, diminished motivation, loss of social support, patient concerns derived from the absence of ongoing monitoring, low self-efficacy and lack of continuity with tailored ExT interventions (Fletcher et al., 2018; Hately & Mandic, 2019; S. Mandic et al., 2015). Therefore, it is mandatory to develop strategies thar can overcame these limitations and provide the necessary support to ensure effective maintenance of regular ExT among patients following the completion of CR program.

In Portugal, as in many other countries, there is a limited availability of CR services for continuous maintenance, corresponding to phase III CR. The availability of accessible and low-cost ExT facilities in the community may be a feasible approach to overcome the above-mentioned limitations and help patients achieve a healthy lifestyle and sustained the benefits achieved during phases II

CR. However, there has been limited investigation of community-based CR maintenance programs, despite suggestions that such programs are safe and can potentially offer the long-term support needed to sustain or improve exercise capacity (Sandra Mandic et al., 2015) and manage cardiovascular (CV) risk factors (Gayda, Juneau, Levesque, Guertin, & Nigam, 2006), reduce hospital readmissions (Taylor et al., 2019) and improve survival (Tegegne et al., 2022).

Therefore, this project aims to respond to these unmet health and social challenges by implementing a specialized phase III CR program to help cardiac patients achieve a sustainable healthy lifestyle, optimal management of CV risk factors, and promote the well-being after phase II CR. The powered primary outcome is the change in peak oxygen consumption (VO_2peak) after 12 months. The secondary outcomes are alterations CV risk factors, physical fitness, PA, QoL, psychological wellbeing, and barriers to CR. We hypothesized that both community CR intervention would be effectives in maintaining and/or improve VO_2peak and other secondary outcomes.

METHODS

Trial design and setting

The study is a single-center, non-blinded, parallel groups, non-inferiority pragmatic non-randomized clinical trial. Cardiac patients will be allocated into two groups: centre-based (CBCR) or hybrid (HyCR) intervention according to their preference. Figure 1 shows a schematic representation of the study protocol. The study will be conducted at the Gymnasium of Faculty of Sport at Porto University (FADEUP). The study was designed conforms with the principles outlined in the Declaration of Helsinki, and according to the Standard Protocol Items Recommendations for Interventional Trials (SPIRIT) (Rivera, Liu, Chan, Denniston, & Calvert, 2020). The study will be submitted to the Ethics Committee of *Centro Hospitalar Universitário do Porto*, where patients will be recruited and to the Ethics Committee of FADEUP, where the study will be performed.

Participants

Participants will include cardiac patients who underwent hospital-based phase II CR at *Centro Hospitalar Universitário do Porto*. Inclusion criteria include male and female age >18 years who had a clinical history of the following conditions or procedures: i) coronary arterial disease in at least one major epicardial vessel; ii) previous MI; iii) coronary revascularization (coronary artery bypass grafting or percutaneous coronary intervention); iv) angina pectoris; or v) chronic HF. Exclusion criteria will be: ii) participants who had heart transplants or ii) inability to exercise or conditions that may interfere with exercise intervention. Relative and absolute contraindications for exercise testing will be assessed before each measurement round followed by compliance with the indications for termination of exercise testing (McDonagh Ta Fau - Metra et al., 2021). Individual participants will be discontinued from the trial if any major surgery or health condition arises that significantly affects their safety to participate in the exercise training program, or if the participant elects to withdraw their consent for any reason, in accordance with their physician's guidance when appropriate. Eligible participants will receive the participant information sheet and sign the participant consent form in the first day of evaluations.

Sample size

Sample size was performed based on change in VO_2peak at 12 weeks, assuming a non-inferiority limit of 1.25 mL/Kg/min. Assuming a VO_2 peak standard deviation of 2.9 mL/kg/min (Pinto et al., 2021). , $\alpha = 0.05$, $1-\beta = 0.80$, and an expected dropout rate at 12 months of 20% (Pinto et al., 2021), the calculations give a total minimum sample size of 160 participants (80 in each group).

As a strategy to reach the appropriate number of participant enrollments and reach the target sample size, a multi-faceted approach will be implemented, including social media promotion, in addition to publicity in *Centro Hospitalar Universitário do Porto* and FADEUP, through pamphlets and in-person communication during cardiology appointments.

To enhance participant retention, a follow-up process will be carried out, involving written feedback and face-to-face dialogue to provide participants with the results. Furthermore, the class schedule will be flexible, allowing participants to make up for missing sessions by attending alternative sessions in case of prior commitments.

Intervention

Two different phase III CR delivery strategies will be offered: CBCR or HyCR according to patient´s preference. This approach recognizes that allowing patients to choose their program model allocation can enhance long-term adherence (Anderson et al., 2017; Shamila Shanmugasegaram, Oh, Reid, McCumber, & Grace, 2013). The program will be offered for 12 months. The supervised sessions will be carried out at the Gymnasium of FADEUP. Exercise training sessions will be monitoring with a heart rate monitor, a mobile app, and with a diary detailing every session completed (hybrid-program).

Patients in both groups will receive a combined ExT program with 3 training sessions per week. Each session will encompass 10 minutes of warm-up with calisthenic and stretching exercise, 25 minutes of resistance exercise (2-3 sets of 12-15 repetitions of each exercise: squat, leg curl, leg abduction, leg adduction, standing calf raise, bench press sitting, seated row, biceps, triceps, lateral raises), 30 minutes of moderate to vigorous aerobic training (intensity corresponding to heart rate at the 1st and 2nd ventilatory thresholds)) and 5 minutes of cool down. Before each supervised ExT session patients will be evaluated by vital signs.

Centre-based group (CBCR): The CBCR group will receive a program at the Gym of FADEUP, which includes 3 sessions per week under the supervision of an exercise physiologist. Exercise training sessions will be monitored with a heart rate monitor (model Polar M200; Polar Electro Ltd). During aerobic training, the speed and inclination of the treadmill will be adjusted to ensure that each training session will be conducted at the prescribed heart rate level. The intensity of resistance training will be gradually heightened based on the rated perceived exertion scale. If patients can comfortably complete the set within an 11-14 rating on the Borg's scale and have the capacity for two additional repetitions beyond the prescribed amount, the intensity will be raised.

Hybrid-based group (HyCR): The HyCR group will perform 4 supervised sessions (equal to those in the centre-based program), once per week at the Gym of FADEUP to familiarize themselves with the training protocol, learn to use wearable device, the mobile app, and how to complete the diary sheet. In addition, a supervised ExT session will be provide once every 2 months to keep patients motivated. Home-based ExT sessions will be monitored with a heart rate monitor (model Polar M200; Polar Electro Ltd). Every exercise session completed by the participant will be recorded by the smartwatch and uploaded to the Polar Flow application. Motivational text messages (SMS) will be sent every week. Phone calls will be made every 15 days in the first 3 months, and every month between the 3 months and 1-year to monitor progress. During phone calls, a semi-structured interview will be carried out with the following aims: i) to verify exercise adherence by comparing self-reported information with data collated from the heart rate monitor; ii) to identify any challenges or barriers impeding the attainment of exercise goals; iii) to offer tailored guidance on adapting the ExT program to the patient's home environment, adjusting exercise intensity, and meeting the recommended prescription, and iv) to provide counseling for lifestyle modification. Patients will be instructed to promptly contact the investigator if they experience any symptoms during or after exercising.

Educational sessions: Once per month, an educational session will be conducted with the aim of maintaining patients' awareness of the behavioral aspects of CVD and how to maintain a healthy lifestyle. The session will be offered to both groups, in person or online via Zoon platform.

Safety: To minimize the risk of adverse events during ExT session, risk stratification will be considered on a case-by-case basis by the Cardiologist. In addition, to deal with possible events, it will be provided a documented emergency plan, which should include contacts of the emergency team, equipment for cardiopulmonary resuscitation (including emergency cart and defibrillator) and referral hospitals. In addition, the CR staff should have certified for immediate life support.

Adherence: defined as the total training sessions attended and successfully completed in accordance with the prescribed training. It will be evaluated by measuring sessions attendance and target heart rate monitor (Polar M200) in CBCR group and through the Polar M200 and exercise logs for the HyCR group. In CR studies, a minimum training attendance rate of at least 75% has been established as necessary to achieve expected results (Beauchamp et al.). Therefore, patients who attend at least 75% of their scheduled exercise sessions will be categorized as adherent, while those who attend less than 75% of the sessions will be classified as non-adherent.

Assessments

Demographic and clinical data

Socio-demographic characteristics (age, gender, marital status, and educational level), clinical characteristics (etiology, left ventricular ejection fraction, New York Heart Association functional class, comorbidities, medication) will be extracted from the patients' clinical records and database systems in the hospital.

Anthropometry

Regarding anthropometric data, body height (cm) will be measured standing upright against a stadiometer (Seca 213). Weight (kg) and body mass index (BMI; kg·m2) will be measured with patients lightly dressed, using a body composition monitor (Tanita, Inner Scan BC 532). Waist circumference (cm) will be measured at the umbilical level.

Outcome measurements

The primary outcome of the study is the change in VO_2peak after 12 months. The secondary outcomes are alterations CV risk factors, physical fitness, PA, QoL, psychological wellbeing, and barriers to CR. Cardiopulmonary exercise test (CPET), CV risk factors, physical fitness, PA, QoL and psychological wellbeing will be assessed at baseline and at 12-months. Barriers to CR will be evaluate at 12-months. The assessment of the outcome's measures is presented in Table 1.

Peak oxygen consumption (VO_2peak)

The primary outcome of the study will be the change in VO_2 peak. The VO_2 peak will be evaluated using the maximum CPET test on a treadmill (Medisoft, model 870C). The test protocol will be chosen according to the patient's PA level and orthopedic/musculoskeletal condition (Naughton, modified Bruce or Bruce). CPET will be performed under medical supervision, with continuous electrocardiographic monitoring throughout the protocol. Using a stationary metabolic cart system (Geratherm® Respiratory Ergostik, under BLUE CHERRY®), respiratory gas exchange measurements will be obtained breath-by-breath and recorded every 30 seconds. Heart rate and blood pressure will be recorded at regular intervals during the test. During the CPET test, patients will be strongly encouraged to achieve an 18 on the Borg's perceived exertion rating (scale 6-20) and a respiratory exchange rate >1.10. VO_2 peak will be determined as the highest value achieved during exercise.

Cardiovascular risk factor

To assess CV risk factors, the following parameters will be measured: i) blood pressure, ii) smoking status iii) blood sample analysis and iv) body composition.

i) blood pressure: Blood pressure will be measured by a trained researcher after the patient has been at rest for 10 minutes in a sitting position. Blood pressure will be measured (Colin, BP 8 800; Critikron, Inc., USA) on the left arm and systolic blood pressure and diastolic blood pressure will be calculated as the average of 3 readings. Additional readings will be taken when differences between readings exceed 5 mmHg (Mancia et al., 2007).

ii) smoking status: Patients will be compared based on their smoking status (never smoked, former smoker and current smoker). Smoking data will be self-reported by patients.

iii) blood sample analysis: All subjects will undergo venous blood sampling collected from an antecubital vein at baseline and after 12 months (including total cholesterol, LDL-c, high-density lipoprotein cholesterol, triglycerides, glucose and HbA1c). Alterations will be evaluated using the standard protocol of our hospital laboratory.

iv) body composition: Regarding body composition, weight (kg), body mass index (BMI; kg/m2), fat mass (%) and fat-free mass (kg) will be measured with lightly dressed patients, using an electronic segmental body composition analyzer (Tanita, BC-418, Tokyo, Japan).

Physical fitness

For physical fitness, we will assess upper body strength, lower body strength/endurance, aerobic endurance (six-minute walk test), lower body flexibility, upper body flexibility and dynamic balance and mobility.

The analysis of isometric upper body strength will be performed through the **handgrip test** using an isometric hand dynamometer *(Lafayette Model 78010, 78011, Indiana, USA)* (Mendes et al., 2017). To perform the test, the patients were seated in a chair with their backs and arms supported. In addition, the elbow was flexed to 90º, with the shoulders neutral and in adduction, and the forearm in a neutral position. Both arms were measured 3 times, and the average between trials was used as the final score for each arm.

Lower limb strength will be assessed using **the 30-s chair stand test (STS-30)** (Rikli & Jones, 2013). Patients will initially be seated in an armless chair with their arms crossed in front of their chest or at their sides. On command, they will be asked to get up and sit down as quickly and safely as possible. The number of repetitions performed in 30 seconds will be recorded.

For the analysis of aerobic endurance, the **six-minute walk test (6MWT)** will be used (ATS, 2002; Giannitsi et al., 2019). It will take place in a 30 m long covered corridor, marked every 3 m with cones. Baseline oxygen saturation, heart rate, brachial blood pressure, and Borg scale rating will be recorded. During the test, participants must walk as fast as they can, stopping or slowing down if they feel the urge to do so. At the end of the test, the Borg scale, heart rate, number of laps and additional distance covered will be recorded.

To assess lower body flexibility, the **chair sit-and-reach test** will be used. For the performance, the subject will be seated in front of a chair, where he will try to reach his toes with his leg stretched out at the knee joint. The distance between the extended fingers and the tip of the toe (+ or -), in centimetres, will be recorded. The best value of two repetitions will be taken for analysis.

The **back scratch test** will be used to assess upper body flexibility. The patient tries to bring his hands together behind his back, leading one hand from above and the other from below. The result is the distance between the middle fingers (+ or -), in centimetres. The best value of two repetitions will be taken for analysis.

Dynamic balance and mobility will be assessed using the **8-foot up and go test (8FUG)** (Rikli & Jones, 2013). In summary, subjects will sit on a chair with their arms up and will be instructed to stand up and walk up to 2.44 m forward, rotate around a cone and return to the starting position as quickly as possible. Each participant will perform the test twice and the best time will be used for analysis.

Physical activity (PA)

Physical activity (PA) will be measured using a triaxial accelerometer *(Actigraph GT3X, Pensacola, FL, USA).* The triaxial activity monitor measures acceleration in three individual orthogonal planes (vertical, anteroposterior, and mediolateral) and provides activity counts as a composite vector magnitude (VM) of these three axes (Sasaki, John D Fau - Freedson, & Freedson, 2011). The VM is the square root of the square of the three separate dimensional axes [(x2+y2+z2)1/2] (Crouter, Horton M Fau - Bassett, & Bassett, 2012). Participants will be instructed to wear the accelerometer over their right hip for eight consecutive days, except during sleep, bathing, and water activities. The accelerometer will be programmed to record triaxial data at a frequency of 30 Hz and periods of 1 second in duration. The ActiLife software *(Actigraph, Florida, USA, version 6.9)* will be used to process the accelerometer data. Data will be downloaded and merged in 60 second epochs. Non-use time will be defined as 90 consecutive minutes of zero counts, with an allowance of 2 minutes of non-zero counts, provided there are consecutive zero count windows of 30 minutes up and down (Choi, Liu Z Fau - Matthews, Matthews Ce Fau - Buchowski, & Buchowski, 2011). Non-use time will be excluded from the analysis. Patients with valid data will be those with a minimum of 4 days with at least 10 hours/day of wearing time. Actigraph output will be given in counts per minute derived from VM. The average minutes/day spent in different PA intensity categories will be determined according to cutoff points that relate PA to counts/min: sedentary time (<200 counts/min) (Aguilar-Farías, Brown, & Peeters), light PA (200-2689 counts/min) and moderate and vigorous PA (MVPA) (>2690 counts/min) (Sasaki et al., 2011).

*Quality of life (*QoL)

Quality of life will be assessed using the 36-Item Short-Form Health Survey (SF-36) (Jette & Downing, 1994). The SF-36 is a widely used instrument for assessing health-related QoL in clinical and research studies measuring 8 dimensions of health: physical functioning, physical role, bodily pain, general health, vitality, social functioning, emotional role, and mental health. The highest score for each parameter of SF-36 is 100, and the lowest is 0.

Psychological well-being

This will be evaluated by the Hospital Anxiety and Depression Scale (HADS) (Pais-Ribeiro et al., 2007). The questionnaire is composed of 14 questions on a four-point (0-3) scale. The possible scores ranged from 0 to 21 for anxiety and 0 to 21 for depression. A score of 0 to 7 for either subscale will be regarded as being in the normal range, a score of 11 or higher indicates the probable presence of the mood disorder and a score of 8 to 10 is just suggestive of the presence of the respective state.

Barriers to CR

Barriers to CR will be evaluated through an interview with the Cardiac Rehabilitation Barriers Scale (CBRS) and will be assessed at the end of the CR programs (12 months). The CRBS questionnaire will be applied by the researcher. This instrument assesses the patient's perception of the degree to which different barriers (health system, health professional or patient barriers) affect their participation in a CR program (Ghisi et al., 2012; S. Shanmugasegaram et al., 2012). The questionnaire consists of 21 questions scored from 1=totally disagree to 5=totally agree. A higher score indicates greater barriers to the CR program. The questions are divided into five subscales, such as comorbidities/functional status, perceived need, personal/family issues, travel/work conflicts and evaluate (Ghisi et al., 2012).

Data collection and management

All procedures will be performed after the patient's authorization by signing the informed consent form. In addition, the collection, storage, and utilization of research data will require explicit authorization from patients. All data will be collected on printed sheets and subsequently entered electronically into a secure Drive, ensuring safe and accessible storage for the study researchers. All physical copies of documents will be securely stored in a locked filing cabinet. Patients will be identified in the database and project-specific documents using a unique study participant number.

DATA ANALYSIS

Primary and secondary outcome variables will be presented as mean and standard deviation or median and interquartile ranges, as appropriate. The normality and homogeneity distribution of the data will be examined by the Shapiro-Wilk test or by kurtosis and skewness test and Levene's test, respectively. Between group differences at baseline and in the change from baseline to the end of the intervention will be tested with unpaired Student t tests or Mann-Whitney U test. Between group differences Analysis of Covariance will be also employed to adjust for baseline differences between groups. Within-group comparisons from baseline to the end of the intervention will be analysed using the paired Student t tests or Wilcoxon signed-rank test. Updated SPSS versions will be used to conduct the analyses. Statistical significance will be set at an alpha level of 0.05.

EXPECTED OUTCOMES

The short-term impact of the project outlined is the maintenance of phase II CR, namely improvements on exercise capacity, physical fitness, PA, QoL and psychological wellbeing and management of CV risk factors. Long-term expected outcomes include the achievement of sustainable healthy lifestyle, with possible reduction on hospital readmission, and improve survival. Long-term impact of this project for the society lies on the implementation of a community-based CR maintenance program that will continue serving patients after the end of the study. So, this proposal is expected to have a substantial social impact on driving CVD management through achievement of sustainable healthy lifestyle, supporting the recommendations of the main cardiac societies (Chew et al., 2016; Thomas et al., 2010; Visseren et al., 2021).

Figure 1. Flowchart of the study protocol. CR: cardiac rehabilitation. CHUP: Centro Hospitalar Universitário do Porto.

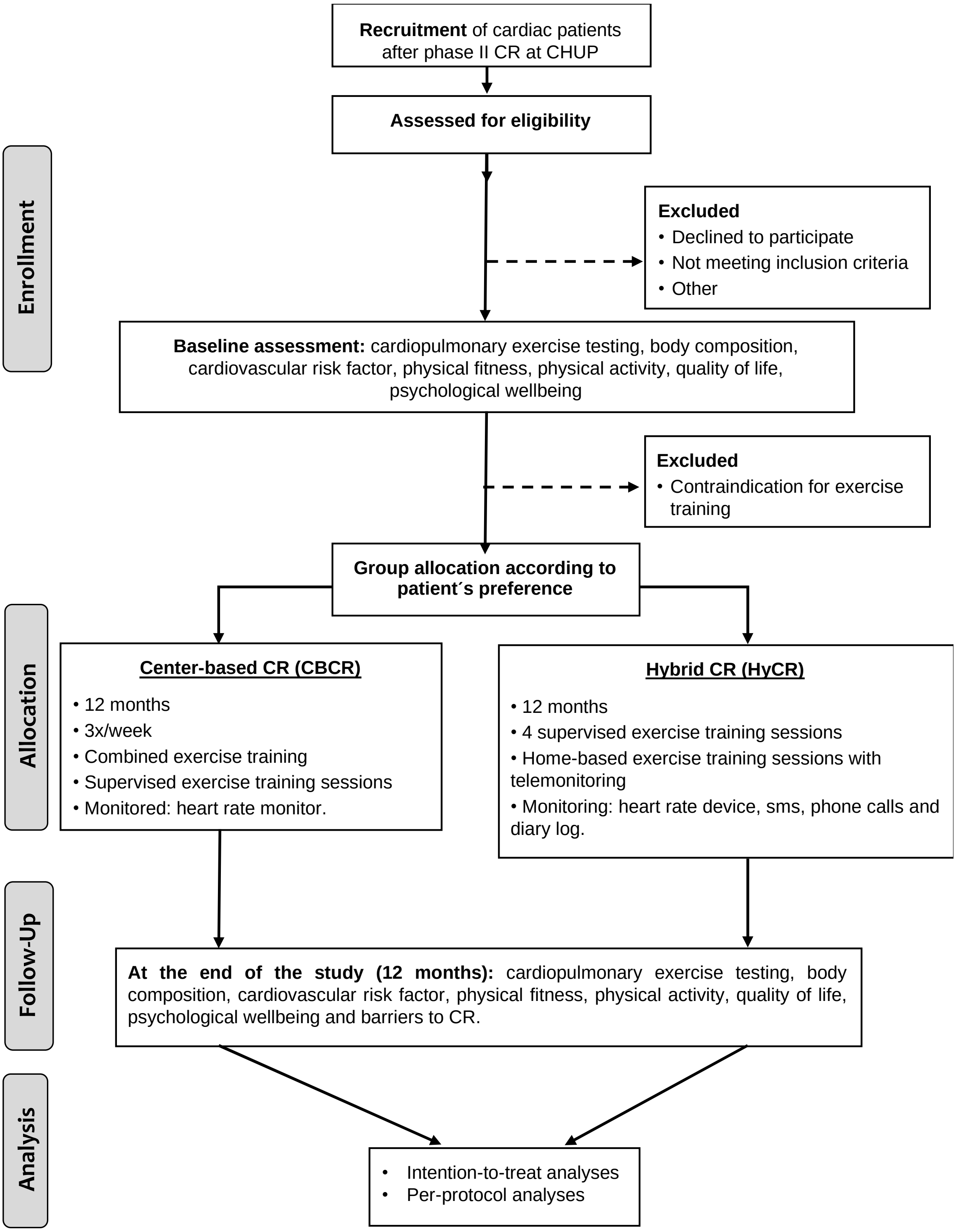

Table 1. Timeline of assessments.

	STUDY PERIOD				
	Enrolment	**Allocation**	**Post-allocation**		
TIMEPOINT	**-t1**	**0**	**T1 baseline**	**T2 T1 to T3**	**T3 12 months**
ENROLMENT:					
Eligibility Screening	X				
Informed consent	X				
Allocation		X			
INTERVENTION					
Centre-based			◆—	—	—◆
Home-based			◆—	—	—◆
Educational sessions				X	
ASSESSMENTS					
CPET			X		X
CV risk factors			X		X
Physical fitness			X		X
Physical activity			X		X
Quality of life			X		X
Psychological wellbeing			X		X
Barriers to CR					X

CPET: Cardiopulmonary exercise test; CV: cardiovascular; CR: cardiac rehabilitation.

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CHAPTER IV

GENERAL DISCUSSION

GENERAL DISCUSSION

Although heart failure (HF) is one of the main causes of morbidity and mortality which affect more than 26 million people worldwide (Fonseca, Brás, Araújo, & Ceia, 2018), there are some gaps in the scope of HF treatment. Despite a variety of pharmacological therapies and devices available, mortality and morbidity rates are still high, and patient's prognosis and quality of life remain poor (Packer & Metra, 2020).

Lifestyle modifications have been shown to help manage HF symptoms and improve cardiac function. These lifestyle changes include cardiac rehabilitation (CR) and regular exercise, smoking cessation, limiting alcohol consumption and sodium intake, and adherence to a healthy diet. International HF guidelines recommended rehabilitation (including patient education, self-care, and exercise training as a Class IA recommendation) as essential component in the treatment of patients with HF (Bozkurt B Fau - Hershberger et al., 2021). However, despite all the scientific evidence and clinical recommendations, CR is an underutilized treatment (Humphrey, Guazzi, & Niebauer, 2014). The reasons for the underutilization of CR programs are multifactorial and include health system, health professional or patient barriers (Sérvio et al., 2019). In addition, contextual differences such as the type of health system organization and reimbursement policies, and patient characteristics and literacy can significantly influence patient-related barriers. Therefore, these factors vary according to the heterogeneity of populations. Thus, considering the importance of CR programs in the treatment of patients with HF, the low accessibility and adherence to this type of program, it is necessary to understand the reasons for this underutilization in the context of the Portuguese population.

Thus, in Study I, we selected the Cardiac Rehabilitation Barriers Scale (CRBS) to describe and compare the barriers to participation in a clinic versus home-based CR program in patients with HF in a public hospital in Portugal. In addition, we investigate whether these barriers were related to CR adherence. The CRBS scale was developed to assess patients' perceptions of the multi-level barriers to CR enrollment and participation (S. Shanmugasegaram et al., 2012). It is considered a key toll for identifying barriers so that they can be effectively mitigated (Chindhy, Taub, Lavie, & Shen, 2020). The CRBS has been translated to 17 languages, including Portuguese (Aljehani, Grace, Aburub, Turk-Adawi, & Ghisi, 2023). However, a limitation of this scale is that it was validated for Brazilian Portuguese, which can cause some difficulty in understanding its translation into European Portuguese. In addition, even though it is valid in different regions and languages, being a reference for assessing barriers in CR, there are pros and cons in using a questionnaire for assessments. For example, the CRBS scale evaluates the patients' perceptions of multi-level barriers (patient, provider, and health system barriers) to using CR, which depend on the patients' recall, which can be biased, especially in older patients. On the other hand, the advantage to use CRBC is that questionnaires are a simple instrument, easily administered, appropriate to use in large samples for research purposes and cost-effective.

In addition to identifying barriers related to participation in CR programs, it is important to address these barriers to ensure that everyone who could benefit from the CR has the opportunity to participate. Improving CR participation requires a multilevel approach that encompasses legislation, national and international guidelines, and local strategies (Clark et al., 2013; Nieuwlaat, Schwalm, Khatib, & Yusuf, 2013). In this sense, home-base CR has emerged as an alternative to overcome the barriers of conventional CR approaches (Anderson et al., 2017). Home-based interventions, alone or in combination with clinic-based CR (hybrid CR), have the potential to address some barriers such as schedule flexibility, time commitment, travel distance, cost, and patient preference (Chindhy et al., 2020). Some studies have promisingly demonstrated the advantages of this exercise modality (Imran et al., 2019; Zwisler et al., 2016).

Home-based telerehabilitation has demonstrated excellent acceptance, safety, effectiveness and with high adherence among patients with HF, including those with cardiovascular implantable electronic devices (Piotrowicz et al., 2015). Considering that CR programs are a cost-effective intervention that results in clinical improvements and that these benefits are independent of the type of program (clinic or home-based), CR at home environment can be an alternative to improve accessibility and adherence to CR. Thus, in Study I, the barriers to participation in a clinic versus home-based CR program were investigated in patients with HF in a tertiary hospital in Portugal.

Our data demonstrated that “other health problems” was the most common barrier to CR reported by almost 50% of patients with HF, regardless of the context in which the CR program was carried out. In fact, these limitations originating from health problems, are common among individuals with HF, indicating the importance of optimizing disease management prior to starting the CR program. Comparing with clinic-based group, the home-based participants rated two main barriers significantly higher, such as “bad weather” (2.07±1.65vs 1.06±0.24 points; p=0.002) and “I have little time” (1.59± 1.37 vs 1.09±0.52 points; p=0.002). In our study, it was observed that over 90% of the patients assigned to the home-based program engaged in outdoor aerobic exercises, such as walking on the street. It should be noted that the prevailing climatic conditions can significantly impact the effectiveness of these programs for patients. In an effort to overcome this barrier, we provided some alternatives to the patients during the weekly phone calls. For instance, we suggested utilizing the car parks of supermarkets or shopping centers as viable locations for carrying out aerobic training, which had been applied by some patients. In addition, when patients from home-based group reported "I have little time", it may suggest that not having a training schedule and commitment to being present in a face-to-face session can be a problem for some patients, being a limitation of home-based programs.

The home-based CR program was designed in the hypothesis that it could increase adherence when comparing with traditional CR programs. However, our data showed similar values in both groups, with 91% adherence in the clinic-based group and 82% adherence in the home-based group. In addition, we found a similar dropout rate (around 19%), corroborating other research on traditional CR programs in Portugal, which showed an abandonment rate bellow 25% (Fontes, Vilela, Durazzo, & Teixeira, 2021). It highlights the high adherence values and low dropout rate from patients in our study, which could indicate a highly motivated population. When we compared non-adherent patients, the home-based group had a higher total barrier score. Even though home-based programs have emerged as a strategy to improve barriers to CR adherence (Winnige, Vysoky, Dosbaba, & Batalik, 2021). However, it is important to note that even though the barrier score was higher in home-based group, it did not impact on adherence rates. These results suggest that while home-based programs can overcome some barriers related to traditional CR programs, there are other barriers that must be overcome. Further investigations and incentives for research into home-based programs to improve the participation rate and address common barriers to delivering home-based CR are needed.

Another gap we had identified relates to the maintenance of exercise training after phase 2 CR. After completion of the phase 2 CR program, patients are encouraged to maintain the exercise training routine on their own to preserve the health benefits achieved. In this sense, long-term adherence to physical activity/exercise training after phase 2 CR seems challenging, but it is essential to maintain cardiovascular health and reduce the risk of future cardiac events (Tilgner et al., 2022). The degree of self-monitoring/management required in home-based programs may promote a favorable transition to sustainable behavioral change and disease self-management (McDonagh Ta Fau - Metra et al., 2021). Therefore, in Study II we analyzed the effectiveness of the home-based CR on exercise adherence and physical fitness after phase II CR in HF patients, and also compared home-based vs clinic-based CR intervention. Our hypothesis was that home-based CR would increase long-term physical activity adherence and maintain and/or improve physical fitness levels.

To measure adherence to physical activity, we used the short version of the International Physical Activity Questionnaire (IPAQ) and a heart rate monitor (Polar M200; Polar Electro, Finland). As physical activity is a multidimensional practice, valid measurements in free-living individuals can be a challenging task, regardless the population. The IPAQ is a feasible method for assessing daily physical activity in large-sample epidemiological studies (Ács et al., 2020). It is commonly used to investigate the relationship between physical activity recommendations and identify appropriate patterns of physical activity for maintaining health benefits (Warburton & Bredin, 2017). The IPAQ is easy to be applied by professionals, is cost-effective, and have a good scientific utility. It is the most widely used questionnaire to obtain internationally comparable data on health–related physical activity for the general population (Craig et al., 2003).

However, the assessment of physical activity by questionnaires is based on self-reports, and therefore, most often biased due to social desirability, inaccurate memory, and the inability to capture the absolute level of physical activity intensity (Ara et al., 2015). Objective measures can help to avoid some biases related to subjective measures, especially in populations with no experience in the practice of physical activity and with limited physical function, as in the case of patients with HF. In our studies we also used an activity tracker (Polar M200, Polar Electro, Finland) to objective measure physical activity. Polar has been a leading brand for consumer-based activity trackers and offer a range of activity tracker equipment utilizing different sensors, including accelerometers, gyroscopes, electrocardiography (heart rate), photoplethysmography (pulse), and global positioning systems (Henriksen, Johansson, Hartvigsen, Grimsgaard, & Hopstock, 2020). However, it is not clear how this Polar wrist-worn activity trackers estimates physical activity metrics, which difficult the comparison with other studies (Henriksen et al., 2020). A recent meta-analysis has showed that in fact studies performed using a Polar device are difficult to compare with other research in the literature (Henriksen et al., 2020). The results showed a large difference in study setting (i.e., device model, measurement duration, lab vs free-living, and reported metrics), few available studies for each Polar model, and occasionally conflicting result for the same model. Hence, we opted for utilizing the IPAQ as the principal tool for quantifying physical activity levels due to the limited validation of comparisons involving Polar activity tracker devices.

To evaluated physical fitness, we selected three tests from the physical fitness test battery proposed by Rikli and Jones (Rikli & Jones, 2013) in addition to handgrip strength. We choose the 6-minute walk test (6MWT) to assess functional capacity, the 8-foot up and go test to assess dynamic balance and mobility, the handgrip strength test to assess upper body strength, and the 30-second chair stand test to assess lower limb strength. These tests are widely used and representative of the different physical fitness components, there are reference standard values for comparison, they are easy to apply on the clinical setting and they are highly related to the daily activity demands (Blanquet et al., 2022; Giannitsi et al., 2019; Schmidt et al., 2020).

In Study II we found that both groups returned to baseline levels of physical activity and physical fitness 1-year after the end of phase II of CR. In fact, most patients are unable to maintain their physical training routine. Poor adherence to exercise training results in reversal of the benefits obtained (e.g., physical fitness and worsening CVD risk profile) (Giallauria et al., 2006; Hansen et al., 2010; Volaklis, Douda Ht Fau - Kokkinos, Kokkinos Pf Fau - Tokmakidis, & Tokmakidis, 2006) and limits the potential of CR to alter patient prognosis. Furthermore, Study II demonstrated that home-based CR did not result in better long-term physical activity adherence or physical fitness levels compared with the clinic-based intervention. This suggests that 12 weeks of a home- or clinic-based CR program would not be sufficient to promote a favorable transition to sustainable behavioral change.

Finally, Study III was proposed with the aim of filling this gap in adherence after phase II of CR. The last European Guidelines for the Prevention of Cardiovascular Diseases highlight the importance to use home-based with and without telemonitoring to increase participation in CR and support behavioral change (McDonagh Ta Fau - Metra et al., 2021). Therefore, the Study III was a study protocol designed to respond to unmet health and social challenges regarding maintenance after phase II CR. It aimed to implement a specialized community-based phase III CR program to help cardiac patients achieve a sustainable healthy lifestyle, manage optimal cardiovascular risk factors, and promote wellness after phase II CR. In this study protocol, two different phase III CR delivery strategies will be offered: clinic-based or hybrid CR according to patient preference. Each of these options will be considered to the individual patient in order to address common barriers to delivering CR such as lack of resources, and geographical and travelling constraints. This approach recognizes that allowing patients to choose their program model allocation can increase long-term adherence (Anderson et al., 2017; Shamila Shanmugasegaram, Oh, Reid, McCumber, & Grace, 2013). In Study I, the fact that patients could not choose which group to participate in may have interfered with the reported barriers. Indeed, recent studies have shown that using a patient-centered approach to program model allocation can serve to promote adherence to CR. We believe that this preferred approach in Study III strengthens our project and, therefore, the expected long-term results include achieving a sustainable healthy lifestyle. Hence, this proposal is expected to have a substantial social impact in conducting cardiovascular disease management through achieving a healthy and sustainable lifestyle, supporting the recommendations of major cardiac societies (Chew et al., 2016; Thomas Rj Fau - King et al., 2010; Visseren Flj Fau - Mach et al., 2021).

Another methodological issue that deserves consideration is the sample size in Study I and Study II, which was small and therefore limits the generalizability of our results. However, we must highlight that the study was performed within a pragmatic approach, being conducted in real-world clinical practice settings, with typical patients and by qualified clinicians. We include patients with peripheral arterial disease, atrial fibrillation, cardiac implanted devices, and older patients, who are generally excluded from the CR studies. In addition, we also include patients with class IV in the New York Heart Association functional classification.

Therefore, our results confirm the need to implement strategies to address common barriers to delivering and adherence to phase 2 CR programs. In addition, new programs within the community are needed to improve long-term physical activity and physical fitness levels to maintaining the gains obtained with CR, resulting in a better quality of life for HF patients.

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CHAPTER V

CONCLUSIONS AND FUTURE DIRECTION

CONCLUSIONS

Based on the general conclusions of each study that were presented in this thesis, it is possible to outline the following major conclusions:

1. “Other health problems” was the most common barrier to CR reported by patients with HF in Portugal, regardless of the context of the CR program undertaken. Home-based group had a higher total score and had two main barriers that were more prevalent than in the clinic-based group, such as “bad weather” and “I have little time”.

2. Although home-based CR programs have emerged as a strategy to improve barriers to CR adherence, they seem to present limitations in our population with similar adherence rates to the clinic-based group.

3. Home-based CR program does not appear to result in better long-term physical activity adherence or levels of physical fitness compared to the clinic-based intervention, suggesting a 12-week CR program at home as well at a clinical setting is not enough to promote a transition conducive of sustainable behavioral change.

4. Low adherence to long-term physical training results in the reversal of the benefits received and limits the potential of CR to change the patient's prognosis.

5. Specialized community-based CR phase III study protocol with allocation of groups according to patient preference may respond to unmet health and social challenges regarding maintenance after phase II CR.

FUTURE DIRECTIONS

Further studies with larger sample sizes and allocation into groups by patient preference are needed to strengthen or refute our findings about the types of barriers and the effectiveness of home-based CR programs in improving long-term adherence.

In addition, it is imperative to implemented effective strategies that address common barriers to delivery and adherence to phase 2 CR programs.

Finally, the development of novel community programs is needed to improve long-term physical activity and physical fitness and to preserve the benefits achieved through CR, ultimately leading to a better quality of life for patients with HF.

APPENDICES

ESCALA DE BARREIRAS PARA REABILITAÇÃO CARDÍACA

ID: ____________
Data: ____________

As perguntas a seguir abordam alguns fatores que influenciam a sua participação em sessões de reabilitação cardíaca. Por favor, responda todas as perguntas desta página independentemente se você já participou ou não de um programa de reabilitação cardíaca

Eu não participo de um programa de reabilitação cardíaca, ou se participo, eu faltei algumas sessões porque:	Discordo Plenamente	Discordo	Estou indeciso	Concordo	Concordo Plenamente
1. Por causa da distância (por exemplo, o programa fica muito longe para o seu deslocamento);					
2. Por causa do custo (por exemplo, de combustível, estacionamento, passagens de ônibus);					
3. Por causa de problemas com transporte (por exemplo, não dirijo e não tenho quem me leve, transporte público inacessível ou ineficiente);					
4. Por causa de responsabilidades familiares (por exemplo, cuidar de netos, filhos, marido, tarefas domésticas);					
5. Porque eu não sabia sobre a reabilitação cardíaca (por exemplo, o médico não me falou sobre isso);					
6. Porque eu não preciso de reabilitação cardíaca (por exemplo, sinto-me bem, meu problema cardíaco está tratado, não é grave);					
7. Porque eu me exercito em casa ou na minha comunidade;					
8. Por causa do mau tempo;					
9. Porque eu acho exercício cansativo ou doloroso;					
10. Por motivo de viagem (por exemplo, férias, trabalho);					
11. Por que eu tenho pouco tempo (por exemplo, muito ocupado, horários de reabilitação inconvenientes);					
12. Por causa das responsabilidades do trabalho;					
13. Por que eu não tenho energia;					
14. Outros problemas de saúde me impedem de frequentar. Especificar: (____).					
15. Porque eu sou muito velho;					
16. Porque o meu médico não achou que fosse necessário;					
17. Porque muitas pessoas com problemas cardíacos não frequentam reabilitação cardíaca, e eles estão bem;					
18. Porque eu posso controlar o meu problema de coração;					
19. Por que eu acho que fui encaminhado, mas o programa de reabilitação não entrou em contato comigo;					
20. Porque demorou muito para que eu fosse encaminhado e iniciar o programa;					
21. Porque prefiro cuidar da minha saúde sozinho, não em um grupo;					
22. Outro(s) motivo(s) para não frequentar um programa de reabilitação cardíaca: ____					

ID:____________

Data:____________

IPAQ versão curta

As questões que lhe vou colocar, referem-se à semana imediatamente anterior, considerando o tempo em que esteve fisicamente ativo/a. Por favor, responda a todas as questões, mesmo que não se considere uma pessoa fisicamente ativa. Vou colocar-lhe questões sobre as atividades desenvolvidas na sua atividade profissional e nas suas deslocações, sobre as atividades referentes aos trabalhos domésticos e às atividades que efetuou no seu tempo livre para recreação ou prática de exercício físico / desporto.

Ao responder às seguintes questões considere o seguinte:

Atividades físicas vigorosas referem-se a atividades que requerem um esforço físico intenso que fazem ficar com a respiração ofegante.

Atividades físicas moderadas referem-se a atividades que requerem esforço físico moderado e tornam a respiração um pouco mais forte que o normal.

Q.1 Diga-me por favor, nos últimos 7 dias, em quantos dias fez atividades físicas vigorosas, como por exemplo, levantar objetos pesados, subir escadas com sacas, jardinagem, ginástica aeróbica, nadar, andar de bicicleta a um ritmo rápido?

☐ Dias

Q.2 Nos dias em que pratica atividades físicas vigorosas, quanto tempo em média dedica normalmente a essas atividades?

☐ Horas ☐ Minutos (por dia)

Q.3 Diga-me por favor, nos últimos 7 dias, em quantos dias fez atividades físicas moderadas como por exemplo, carregar objetos leves, dar banho aos animais de estimação, andar de bicicleta a um ritmo normal ou brincar com os netos? Por favor não inclua o "andar".

☐ Dias

Q.4 Nos dias em que faz atividades físicas moderadas, quanto tempo em média dedica normalmente a essas atividades?

☐ Horas ☐ Minutos (por dia)

Q.5 Diga-me por favor, nos últimos 7 dias, em quantos dias andou/caminhou?

☐ Dias

Q.6 Quanto tempo no total, despendeu num desses dias, a andar/caminhar?

☐ Horas ☐ Minutos (por dia)

Q.7 Diga-me por favor, num dia normal quanto tempo passa sentado? Isto pode incluir o tempo que passa a uma secretária, a visitar amigos, a ler, a estudar ou a ver televisão.

☐ Horas ☐ Minutos (por dia)