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ADDITION OF AULA DE REHABILITACIÓN CARDIACA VERSUS CENTER-BASED CARDIAC REHABILITATION PROGRAMS ALONE. EFFECTS ON THE QUALITY OF LIFE OF WOMEN AFTER ACUTE CORONARY SYNDROME

A RANDOMIZED, OPEN-LABEL CLINICAL TRIAL

MERCÈ POL CAMPS
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I warmly thank all the team from the *Cardiology Service* at *Hospital Universitari Doctor Josep Trueta* for having me and teaching me so much during my internship.

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«Maleït sigui aquest muntatge inútil que ens ha robat mitja vida, maleïda la idea del sacrifici i la velocitat i haver de fer més, sempre més i més»

-Najat el Hachmi, Dilluns ens estimaran

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1. ABBREVIATIONS

AulaRC	Aula de rehabilitación cardiaca
ACS	Acute coronary syndromes
AMI	Acute myocardial infarction
AHA	America Heart Association
CHD	Coronary heart disease
CR	Cardiac rehabilitation
CRP	Cardiac rehabilitation program
cTn	Cardiac troponin values
CV	Cardiovascular
CVD	Cardiovascular disease
CVR	Cardiovascular risk
ECG	Electrocardiogram
ESC	European Society of Cardiology
HBCRP	Home-based cardiac rehabilitation program
HF	Heart failure
HRQOL	Health-related quality of life
HUDJT	Hospital Universitari Doctor Josep Trueta
IHD	Ischemic heart disease
JAHA	Journal of American Heart Association
LV	Left ventricle
MI	Myocardial infarction
NSTEMI	Non-ST-segment elevation myocardial infarction
PE	Physical exercise
QoL	Quality of life
SEC	Sociedad Española de Cardiología
STEMI	ST-segment elevation myocardial infarction
WHO	World Health Organization

2. ABSTRACT

ADDITION OF AULA DE REHABILITACIÓN CARDIACA VERSUS CENTER-BASED CARDIAC REHABILITATION PROGRAMS ALONE. EFFECTS ON THE QUALITY OF LIFE OF WOMEN AFTER ACUTE CORONARY SYNDROME

Background: Cardiac rehabilitation programs are strongly recommended in guidelines, but for diverse reasons, women are less likely to be referred than men after an acute coronary syndrome. Even after being referred, women show lower rates of enrolment and completion. Clinical outcome improvements are at least as great in women as in men. When overcoming completion barriers, solutions are reducing the time of enrolment, information campaigns about benefits, increase privacy with women-only programs, a wider variety of exercise modalities, family support, and alternative cardiac rehabilitation models.

Objective: The aim of this project is to demonstrate that the use of *Aula de rehabilitación cardiaca* added to current cardiac rehabilitation programs offers better outcomes in terms of *quality of life in women* who suffered an *acute coronary syndrome*.

Design: We will conduct a *randomized, open-label, controlled, clinical trial* including 208 patients who will be assigned to either participate in *Aula de rehabilitación cardiaca* in addition to centre-based cardiac rehabilitation program or receive cardiac rehabilitation alone. This study will be conducted over a period of four years. During this time, we will assess and compare the changes in the health-related quality of life, depression, and anxiety symptoms of all the participants.

Setting: This study protocol will take place in *Girona, Catalunya*.

Participants: The participants will be women adult patients with coronary heart disease who do not show contraindications for physical exercise and have access to internet connection. We will invite the patients of *Hospital Universitari Doctor Josep Trueta*, who meet the criteria to participate in the trial from June 2022 to August 2023.

Methods: A *non-probabilistic consecutive method* will be used. 208 patients will be assigned randomly to one of the two groups on a 1:1 ratio: Control group n = 104 and intervention group n = 104. A two-year follow-up will be carried out.

Key words: Cardiac rehabilitation. Aula de rehabilitación cardiaca. Coronary heart disease. Quality of life. Women. SF-36. Zung. STAI.

3. INTRODUCTION

For the aim of this study, we must be able to understand the scope of the problem related to acute myocardial infarction (AMI) in women. But first, we will start by stating some general facts about acute coronary syndromes (ACS).

3.1 ACUTE CORONARY SYNDROMES

Coronary artery disease (CAD) is the single most common cause of mortality in adults. The global burden of cardiovascular disease is increasing, and it is stated that a myocardial infarction (MI) occurs every 43 seconds in the United States. The costs to the health system also reflect the significance of the issue with approximately $ 11 billion spent on MI costs in 2011 (1). The average cost for a ST-segment elevation MI in Spain was estimated at 14000 euros per patient (2).

The majority of ACS share a common physiopathology related to acute myocardial ischemia due to the complication of atheroma plaques. This is the rupture or erosion, with subsequent thrombosis of the atheroma plaque, to which we can add coronary spasm and embolization of thrombotic fragments. Amongst these plaques, the ones with more lipidic content and thinner fibrous capsule are the ones at higher risk of causing an ACS (3).

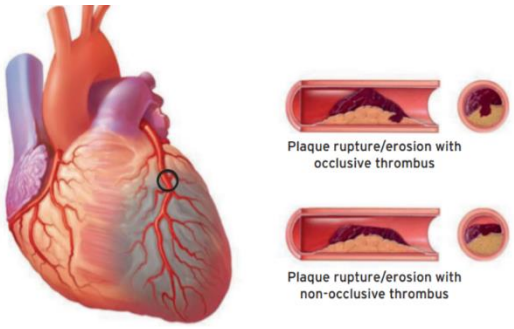

FIGURE 1. ACS physiopathology showing plaque complications (3)

Other multiple interacting factors as fissuring or vasospasms can cause an abrupt loss of blood flow to the cardiomyocytes followed by ischemia. All these factors lead to an increased risk of necrosis of myocardial cells and cardiac death. Consequently, an accurate and fast diagnosis is necessary to know the type of ACS, as they diverge in severity, and we must do proper management. Gathering clinical information, ECG findings, and laboratory results, we must distinguish between the following: *unstable angina, non-ST-segment elevation myocardial infarction (NSTEMI), and ST-segment elevation myocardial infarction* (STEMI) (1).

- When there is a complete occlusion, leading to a transmural infarction (with evidence of elevated cardiac troponin values (cTn)), we call it **STEMI**.
- When there is a subtotal or intermittent occlusion caused by thrombus embolization, we find *unstable angina* or *NSTEMI*. ***Unstable angina*** requires the absence of an elevation of cardiac troponin levels and one of the following criteria: rest angina for more than 20 minutes, new-onset severe angina (<2 months) at least Canadian Cardiovascular Society III or higher, and crescendo angina (angina of increasing frequency, precipitated by less degree of exertion or more severe characteristics) in a patient with previous stable angina. On the contrary, we will find ***NSTEMI*** due to the presence of an elevation of cardiac troponin (3, 4).

3.1.1 Myocardial infarction definition

The term acute myocardial infarction is used when there is an acute myocardial injury with clinical evidence of acute myocardial ischaemia and with detection of a rise and/or fall of cardiac cTn values with at least one value above the 99th percentile upper reference limit and at least one of the following:

- Symptoms of myocardial ischaemia
- New ischaemic ECG changes
- Development of pathological Q waves
- Imaging evidence of new loss of viable myocardium or new region abnormality consistent with ischaemic aetiology

3.2 ACUTE MYOCARDIAL INFARCTION IN WOMEN

As we said before, cardiovascular disease (CVD) and more specifically ischemic heart disease is the leading cause of mortality in the general population and for women globally.

It is also a major contributor to morbidity and healthcare expenditures. That is in part due to the improvement of fatality rates that increases the prevalence of post-myocardial infarction conditions (6, 7).

Consequently, there has been great progress in reducing CVD mortality in women. Nevertheless, most medical research until 2000 has neglected the health needs of women, apart from reproductive concerns, as sex differences due to biological factors and gender differences affected by a wide spectrum of social, environmental, and community factors (8).

3.2.1 Epidemiology of AMI

When we look at the numbers in Spain, we find that about 100-1000/100000 women have suffered a myocardial infarction each year, 10 is for 25-74 years and 100 for >75 years (9). Regardless of age, more women than men will die within one and 5 years of a first AMI, being only partially explained by differences in age, MI risk factors, clinical presentation, and treatment. Some factors to consider are the following:

- **Age**: Recent data suggest that patients below 65 years old have a nearly 2-fold higher crude 30-day hospital readmission rate compared with men of a similar age. First AMI in women usually happens at an older age due to the protective role of oestrogens on the vascular endothelium. Depletion at menopause increases lipid deposition and endothelial dysfunction which can precipitate the development of atherosclerosis over time. Even so, poor outcomes in younger women must be further studied, and they could be explained by sex-specific biology and disease manifestation and various psychosocial stressors that interfere with health behaviours and with biology.
- **Racial disparities:** Ethnically diverse women present with MI at a younger age, the prevalence of MI is higher in black women compared to all the other groups, they also have a higher incidence of sudden cardiac death (SCD) and one-third of the survival rate in white counterparts after out-of-hospital arrest. In addition, half of the black and Hispanic women have a clustering of 3 or more risk factors such as DM, hypertension, or obesity. Thus, the relatively low cardiac mortality in Hispanic women is a paradox and it is thought to be partially explained by greater social support, optimism, and strong family ties, emphasizing the importance of improving quality of life and social support in patients, as well as the efforts made in secondary prevention.

Pathophysiology of AMI

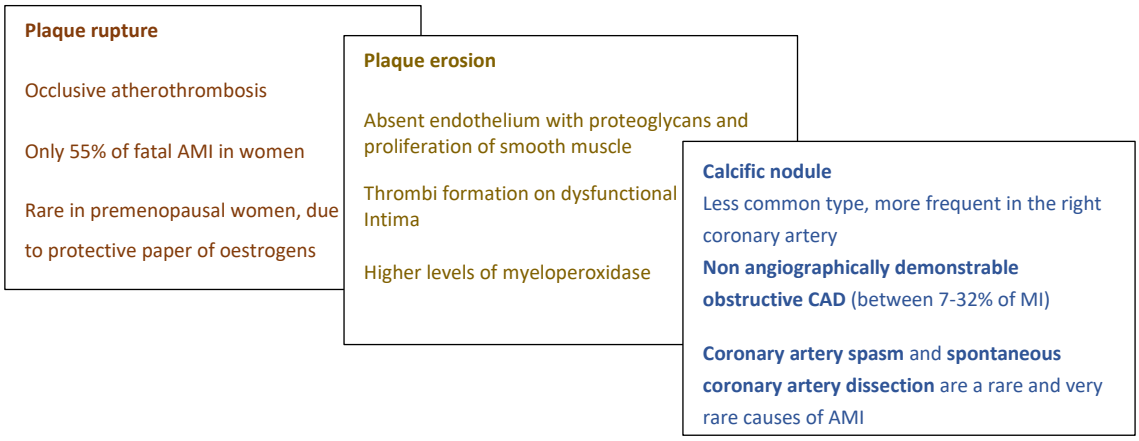

FIGURE 2. Pathophysiology of AMI in women includes plaque rupture, plaque erosion, calcific nodule, non-obstructive CAD and coronary spasm and dissection (8)

3.2.2 Cardiovascular risk factors

Studies have reported a higher prevalence of diabetes mellitus (DM), hypertension, depression, and renal dysfunction in women compared with men.

- **Cigarette Smoking:** Is the single most important preventable cause of MI in women, increasing the risk 7-fold and being the leading cause of MI in women >55 years.

- **Hypertension:** >185 mmHg systolic blood pressure increases the risk 3-fold in cardiac death compared with women with less than 135 mmHg. Also, if it was eliminated as a risk factor, MI could be reduced by 36%.

- **Dyslipidaemia:** Elevated levels of total cholesterol and low-density lipoprotein predict cardiac death in middle-aged and older women (less and more than 65 years) but sex-specific data examining lipids at admission and AMI outcomes are lacking.

- **Obesity and Type 2 DM:** prevalence of obesity is rising year by year and about one-third of US women are obese, ascending to half population among black women. This fact increases coronary risk reaching a 3-fold higher risk or even a 5-fold if associated with the metabolic syndrome, compared with non-obese women. Risk also goes up when DM (diabetes mellitus) is associated, being an especially powerful risk factor in young women, increasing their risk of CHD, including ACS, by 4- to 5-fold.

- **Depression and Other Psychosocial Risk Factors:** An adjusted odds ratio of 3.5 was found in the INTERHEART study, with exposure to psychosocial risk factors, including depression, perceived home/work stress, low locus of control, and major life events. Higher stress scores were perceived by younger women. High stress at baseline was also associated with worse recovery in several health events 1 month after AMI.
  Furthermore, depression, known to be about twice more prevalent in women than in men in the general population, increases a woman's risk for MI or cardiac death by at least 50% (10).

Aside from classical risk factors, we find that there is a disproportion in the rate of women with lower levels of education and socioeconomic status. This is also significant in cardiovascular pathogenesis as it creates an unfortunate environment. Even for the same educational levels, unemployment rates are higher in women for any age level and educational level, and this relates to less wealth and more chronic stress in higher prevalence as health determinants.

In addition, even when they work for the same level, they have lower salaries than men. Finally, even with a higher unemployment rate, the level of work in women is higher when considering domestic work and caregiving, with the fact that these works are not paid nor considered employment. All these psychosocial factors influence CV health, risk, and disease in women (11).

Talking about chronic stress, the levels perceived by women are significantly higher than in men. One in two women feels stressed frequently or continuously vs one in three men. In addition, the levels of anxiety for any age are much higher in women than in men, and the proportion of women with depression doubles the one in men (12).

3.2.3 Clinical presentation

Women normally describe AMI symptoms in a proper way, but they do an inaccurate symptom attribution. Also, the lack of awareness of risk is a factor associated with delay in identifying those symptoms as related to an acute coronary syndrome. That's why guidelines and educational material should be updated to minimize the risk of underdiagnosis and treatment of women with myocardial infarction (13). In fact, what some investigations found was that both young women and their health care providers did not think that symptoms were heart-related and that happened for half of the women as compared to one-third in men (14).

Nevertheless, sex differences exist in the clinical symptomatic spectrum in patients with ACS, while at the same time they showed that there is an overlap in other symptoms between men and women, and a substantial one.

Symptoms more frequently observed in women were between the shoulder blades pain, shortness of breath, nausea or vomiting, neck pain, palpitations, and jaw pain, compared with men. Chest pain and diaphoresis had higher odds of presenting in their male counterparts instead. Yet, both presented most often with chest pain (79% of men and 74% of women) (13).

Still, prehospital median delay in seeking treatment for symptoms of AMI ranges from 2 to 5 hours, exceeding AHA the recommendations by hours, not minutes.

TABLE 1. Factors associated with delay. Adapted from (8)

FACTORS ASSOCIATED WITH DELAY		
Lack of awareness of risk	*Inaccurate symptom attribution*	*Barriers to self-care*
Older age	*Female sex*	*Black or Hispanic race*
Lower education level	*Lower socioeconomic level*	*History of angina, HF*
DM, hypertension, dyslipidaemia	*Living alone*	*Fear and embarrassment*

3.2.4 Treatment

Women are less referred for appropriate treatment during AMI compared with men regardless of proven mortality benefits. Women have worse outcomes but often due to other confounding risk factors. The most favourable outcome in the setting of STEMI is performing a percutaneous coronary intervention (PCI), compared with thrombolytic therapy. In the case of NSTEMI, patients benefit from an early invasive strategy depending on their GRACE risk score.

In the adjacent table we can see the main relevant aspects for our study related to AMI treatment, apart from reperfusion strategies:

TABLE 2. Treatment after AMI. Adapted from (8)

Medical management	*Reduced risk of recurrent ischemic events with aspirin, thrombotic complications with antithrombotic agents* *Increased bleeding risk in women with antiplatelet and antithrombotic agents* *Women with NSTEMI should be managed with the same pharmacological therapy (aspirin, $P2Y_{12}$ receptor inhibitors, anticoagulants, statins, β-blockers, and ACE inhibitors) as men in the acute setting and for secondary prevention*
Aggressive behavioural interventions	*Smoking cessation* ***Referral to a comprehensive CR program that includes education on lifestyle and stress management, appropriate weight maintenance, dietary changes, and physical activity***

3.2.4.1 Cardiac Rehabilitation Referral and Participation

CR is an essential component of comprehensive care after AMI, is internationally validated and integrated into evidence-based guidelines for women, and has undeniable morbidity and mortality benefits, being Class I recommendation in ESC Guidelines (Annex I) (16).

CR is known to improve depression in women although depressive symptoms are linked to suboptimal CR attendance, and 2-fold increased risk of non-completion. Women absent from CR include unmarried, socioeconomically disadvantaged, smokers, depressed, obese, sedentary, elderly, and those with less education, less social support, and striving family obligations (8).

3.2.4.2 Sexual Counselling

Compared with counselling for men, sexual dysfunction among women after an AMI has received less attention and only about 12% of women reported discussing sexual activity with a physician in the month after AMI, according to the VIRGO study. Those who did were usually given restrictions not supported by evidence-based guidelines.

Furthermore, psychological factors as fear, anxiety, and depression, can negatively influence the sexual activity of women and their partners after an AMI. Thus, sexual counselling should begin with a face-to-face discussion addressing problems with the physician and CR is an ideal ambiance in which to discuss within the context of exercise recommendations (8).

3.2.5 Prognosis- Psychosocial risk factors

Women have a disproportional burden of psychosocial risk factors even though indicators of AMI severity are similar or more favourable in women compared with men of similar age. Emerging evidence recognises depression as a prognostic factor after ACS, with a prevalence of about 20% in post-MI patients, several times higher than in the general population and twice as high as in men with MI. The numbers go up to >40% of post-MI women between 50 and 60 years of age and half of <50 years of age ones meeting the diagnostic criteria for major depression. Recent evidence links depression to mental stress-induced ischemia, which gives a 2-fold increased risk of mortality or recurrent events in patients with IHD.

On the contrary, social support is an important mitigating factor in post-MI recovery, experiencing better mental functioning, a better quality of life, and fewer depressive symptoms at 12 months. The future challenge is to determine what interventions would improve perceived health status among young women in the year after AMI (8).

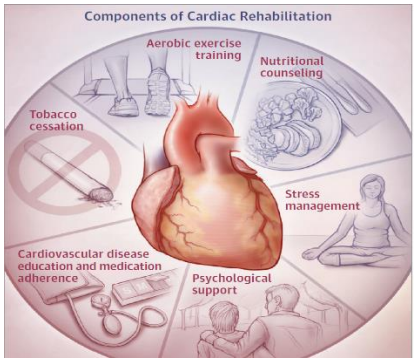

FIGURE 3. Components of CR include physical, nutritional, risk factor, and psychosocial interventions (17)

4. OUR INTERVENTION

4.1 CARDIAC REHABILITATION PROGRAMS

CR is a multicomponent and multidisciplinary approach in secondary CV prevention, aim at reducing adverse outcomes in patients with ACD or HF and it can also improve the HRQoL and adherence to lifestyle and medications (17). It is supported but a very strong body of evidence and very strong recommendations and guidelines in both coronary disease and heart failure (18, 16). Even though, the implementation of such programmes in Europe and in Spain is very low, being less than one third of the patients with indication (19).

We find three main interventions in CRP:

1. ***Physical exercising***

Aerobic exercise training in a classic gym is the cornerstone of CR and is of minimal risk in patients with cardiovascular disease and it reduces cardiac mortality (17). There are many benefits from physical exercising (PE): improved endothelial function, reduced thrombogenic risk, improved capillarity of coronary arteries, better collateral circulation, higher levels of oxygen in the blood, decreased inflammatory activity, decrease of dyspnoea, higher vital capacity, better diaphragmatic movement and decrease in stress, depression, and anxiety.

Before PE, patients must undergo a cardiac stress test to evaluate exercise capacity and the risks associated. Using this test we will get information about the *intensity of the exercise*, as the heart frequency should be 75-80% of the patient's maximum or of the point where electric variations manifest if they do, the *risk of arrhythmias,* and the *inadequate responses to exercise.* We also use the Borg exercise intensity scale (Annex II), without overcoming punctuation of 9-14.

The recommendation of the ESC, if there are no abnormalities in the stress test, is 30-40 minutes of moderate-intensity aerobic exercise at least five times per week.

It is also important to be aware of the contraindications of PE:

- *Absolute contraindications for PE*: advanced hypertrophic cardiomyopathy and thrombosed dissecting aortic aneurysm. Even in these cases, low levels of aerobic exercise could be recommended always below medical supervision.
- *Temporal contraindications for PE*: coexistence of acute comorbidities or decompensated cardiologic problems (20).

2. Psychological interventions

Early intervention may improve the patient's quality of life substantially, as emotional disorders after CHD are very frequent with patients being scared, fearing death, and feeling depressed. The psychological intervention in CRP decreases patients' mortality and the risk of a second myocardial infarction (21).

In addition, depression and anxiety intervention strategies should be incorporated in cardiac rehabilitation programmes, as it has benefits on its symptoms, and elevated levels of depression are associated with impaired quality of life (22).

Finally, stress management can be very beneficial. Cognitive behavioural therapy focused on stress management showed a 41% lower rate of fatal and non-fatal first recurrent cardiovascular disease events than the control group (23).

In conclusion, psychological distress makes the completion of cardiac rehabilitation difficult. Patients need to be assessed early in the intervention so that depression and anxiety can be identified and managed. Completion of the program is advantageous because it is associated with improvement in all measured variables (depression, anxiety, and quality of life) (24).

3. Patient's education

It is of major importance in CRP that health care practitioners' advice on how to improve patient's health behaviour and therefore their health condition. Special emphasis should be placed on the risk factors control: HT, dyslipidaemia, glucose blood control, diabetes, and smoking cessation. To do so, we must provide clear information about their health condition, so patients take responsibility and increase autonomy. Details about the drugs they got prescribed as well as the components of cardiac rehabilitation and how they operate in the body and why it is important to keep taking or doing these secondary prevention strategies likely increase the patient's compliance.

4.1.1 TYPES OF CRP

We have two main kinds of CRP:

- ***Non-supervised training programs*:** these are based on an exercise protocol of increasing intensity that patients must do on their own. These address low-risk patients who have no ischemia, no arrhythmias, left ventricle function higher than 50%, and good functional capacity.

- ***Supervised training programs***: these take place in a CR unit and last two to six months in which the patient is guided in how to do the exercises and receives educational and psychological support. There is a training period as patients must try to keep fit and control their risk factors after the program ends. Supervised training programs are divided into intensive, and ambulatory-based (20).

4.1.2 PHASES OF CRP

- ***Phase I:*** It takes place while the patient is still an inpatient (1 to 14 days depending on the severity of the cardiac event). It includes a combination of counselling and reassuring for risk factor modification, medication adherence and education, and how to resume daily activities. In these phases, we complement these measures with early mobilisation to decrease bed rest times and allow as soon as possible basic self-care at discharge from hospital. Active engagement here improves phase II programmes results.
- ***Phase II:*** It involves outpatient patients attending hospital-based programmes during a 6- to 12-week period, providing initial physical, psychological, and social assessments and education to get long-term cardioprotective effects.
- ***Phase III:*** It is community-based and aims to maintain activity beyond the period of subacute care to provide long-term benefits of exercise and minimise the risk for secondary events. For this, it is essential to continue with lifelong training (25).

4.2 HOME-BASED CARDIAC REHABILITATION PROGRAM

Home-based cardiac rehabilitation (HBCR) programs appear as a need for alternatives to current CRP for the last ones being underused. In several studies is concluded that HBCR may be a reasonable option for selected clinically stable low to moderate-risk patients who are eligible for CR but cannot attend a traditional centre-based CR program. Furthermore, the European guidelines on CVD prevention state that HBCR with and without telemonitoring holds promise for increasing participation and supporting behavioural change.

Either alone or in combination with CBCR, HBCR represents a possible alternative that may improve the delivery of CR to eligible patients as it could help overcome some logistical barriers, even more evident in women as we will discuss in the pages below. This is because HBCR services can potentially be used 24 hours a day, 7 days a week, in their home, work, or community environments. The five core components of HBCR are patient assessment, risk factor management, exercise training, dietary counselling, and psychosocial intervention (26).

Furthermore, the current situation in the wake of the **Covid-19 pandemic** makes clear the need to look for alternatives to centre-based cardiac rehabilitation programmes, especially in times of confinement.

4.3 CR IN WOMEN: Facts

CR reduces the patient's cardiovascular morbidity and mortality by 30-50% and is the most effective intervention that can be carried out in patients with heart disease, as we previously said. It is known that there are no differences in the benefits of CR programmes by age or gender. However, there are many barriers limiting women's access to CR, that have recently been described.

In the face of barriers, solutions that improve inclusion have been defined with recommendation level (Annex I). These are:

- Automatic and active referral (I)
- Quick and easy accessibility (IIa) (each day of delay in attending the CR programme means -1% inclusion)
- Appropriate health advice (IIa)
- Home-based programmes (IIa)
- Use of smartphones (i) and telemedicine (IIb)

The decrease in mortality in women completing the CR programme at 12 years is 76% compared to 50% in men(27).

Thus, we are facing a gender gap as CRPs are strongly recommended in guidelines, but for diverse reasons, women are less likely to be referred to CR than men after an ACS. Even after being referred, women show lower rates of enrolment compared to men. Many reasons may be involved but we know that there are gender differences in treatment after an AMI and in The Netherlands database registry, they found that medication adherence was lower in women, in younger patients, and in elderly patients, specifically in NSTMI patients (19).

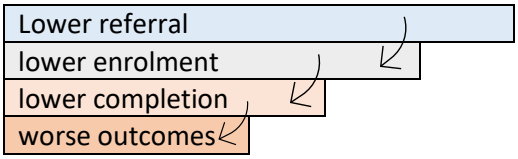

FIGURE 4. Barriers in CR in women(29)

Even so, clinical outcome improvements are at least as great in women as in men (29, 30). The higher benefit with the greatest reduction in mortality is observed in women that complete the program (27).

4.4 CR IN WOMEN: Barriers

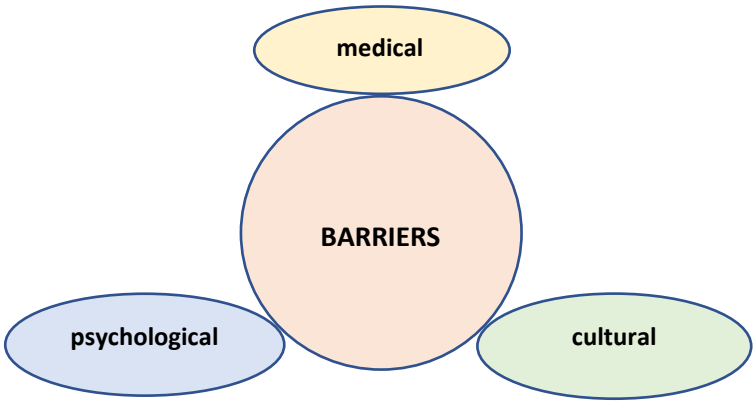

FIGURE 5. Main barriers when in access to CRP.

We find several types of barriers (Table 3), some at a patient level, like the fact that even nowadays and in many cultures usually women are more focused on taking care of the rest of the family than themselves; and some at the caregiver level, as half of sex differences referral can be attributed to true discrimination, consciously or unconsciously (31).

When considering the predictors of non-referral and non-completion we find *age >75 years, DM, HT, CRD, CHF, COPD, and systolic heart failure*. Here, we are facing a contradiction, because the women that are more in need are the less referred (27). It describes the treatment-risk paradox, as patients with poor functional capacity or psychological symptoms are less likely to have access to evidence-based therapies. CR is beneficial irrespectively of functional and psychological status, being even more effective in these women (32).

TABLE 3. Referral and completion barriers in women accessing CRP (29)

REFERRAL BARRIERS	COMPLETION BARRIERS
- The excess of CV morbidity and mortality experienced by women with CAD is under-appreciated by health care practitioners - Lack of strong physician recommendations of referral to CR - Misconceptions of CR - Poor availability of CR facilities	- Comorbidities or older age - Women's lack of information on or familiarity with CR - Negative beliefs or perceptions about CR: *perception of exercise as tiring or painful* - Social factors*: transportation, family obligations, lack of social support, financial concerns*

4.5 CR IN WOMEN: Solutions

Whenever every patient having an ACS is automatically referred to CR, following systematic and liaison-facilitated strategies, it results in the greatest enrolment rates (33).

Therefore, there is a need to make cardiac rehabilitation more accessible, with fewer waiting lists, starting as soon as possible after the cardiac event, because there are longer waiting times in women and each day of enrolment delay translates into a 1% decrement in the likelihood of CR enrolment (34).

Some studies consider women-only programs, home-based and other specific programs more appealing such as Zumba online. Home-based ones could target specific patients that are less likely to complete as racial, ethnic, or economically disadvantaged individuals or women (35,36).

Accordingly, we want to overcome these referral barriers by doing an automatic CR referral, an early posthospital enrolment, and using CR referral and completion rates as a quality marker of the services. When overcoming completion barriers, we will use reducing the time of enrolment, information campaigns about CR benefits, increase privacy (women-only programs), a wider variety of exercise modalities, family support, and alternative CR models (29). Here is where our intervention will be focused, as we explain on the next page below.

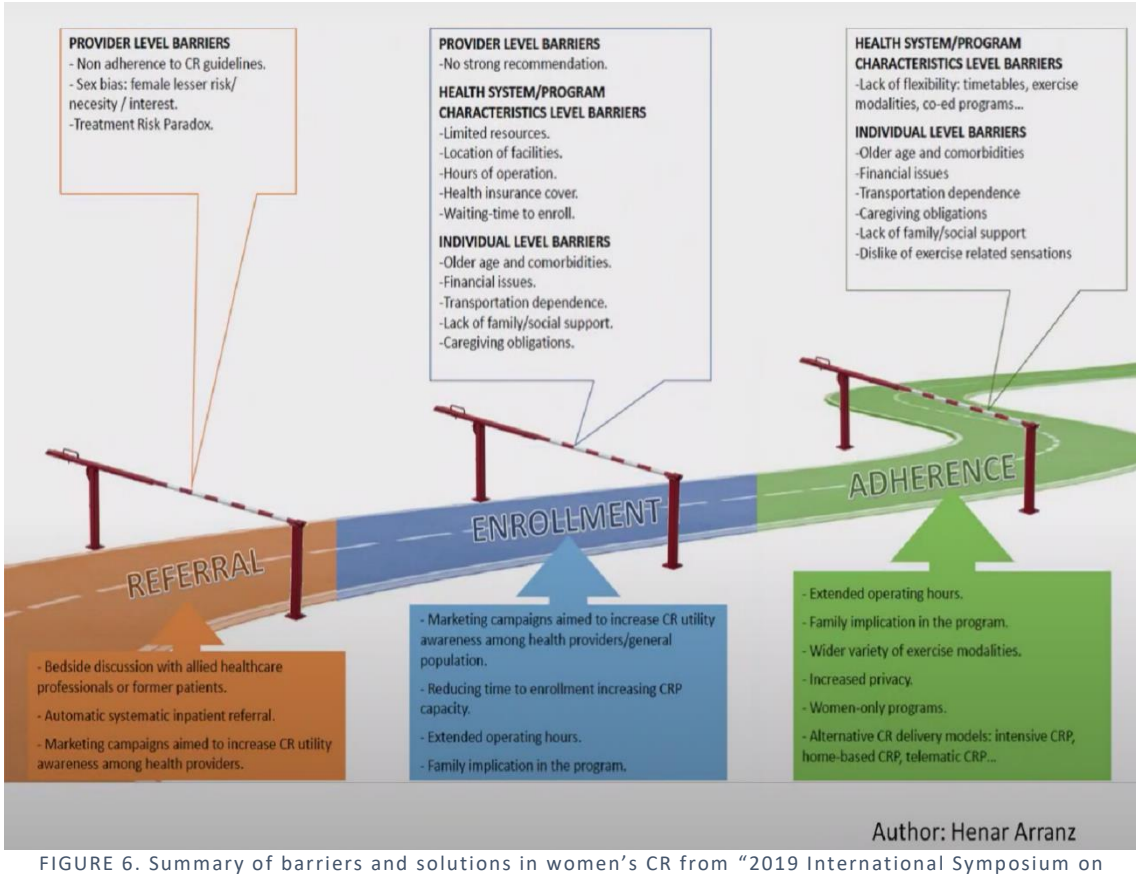

FIGURE 6. Summary of barriers and solutions in women's CR from "2019 International Symposium on Cardiovascular disease in women. Barcelona"

4.5.1 Aula abierta de rehabilitación cardiaca

Aula de rehabilitación cardiaca (AulaRC) is an online cardiac rehabilitation programme that can be used by all patients who cannot access a face-to-face or e-supervised programme or have had to interrupt it. It is an open classroom, free of charge, available 24 hours a day, 365 days a year for training, self-care, and exercise from home even in times of confinement (Annex III).

Contents of Aula abierta RC

In the AulaRC platform for patients we find different sections where the patient can watch videos and carry out the proposed activities:

- ***Interview***: "Why do cardiac rehabilitation". It consists of a 17-minute video in which the benefits and importance of CR are explained.

- ***Introduction***: "What is cardiac rehabilitation". It consists of a 20-minute video where a cardiologist speaker explains CR.

- ***Presentation of the AulaRC platform***: in this section, we find 4 videos that explain the platform: "Objectives and functioning", "Measurement of pulse and heart rate, use of the pulsometer and measurement of blood pressure", "Learning of Borg sensation", and "Learning of alarm symptoms to consult".

- ***Educational programme***: Includes the videos "How the heart works", "What you should know if you have ischaemic heart disease", "What you should know if you have valvular heart disease", "What you should know if you have heart failure", "Cardiovascular risk factors: objectives and control", "Smoking", "Mediterranean diet and weight control", "Drugs and adherence to medication", "Sexual dysfunction", "Expert patient", and "Work advice".

- ***Training programme:*** Includes the videos "Importance of exercise in heart disease", 2 videos of "Adapted home aerobic activity and strength" and two videos of "Suggested out-of-home aerobic activity and strength".

- ***Psychological therapy:*** With videos on "Emotions", "How to handle stress", "Relaxation techniques 1", and "Relaxation techniques 2" (37).

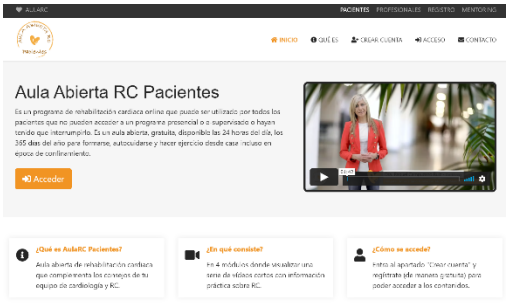

FIGURE 7. General view of AulaRC webpage: https://aularc.es/

4.6 QUALITY OF LIFE

Quality of life measures are increasingly becoming accepted as a useful and successful tool to measure outcomes in cardiac rehabilitation.

The health-related quality of life (HRQoL) includes physical impairment and symptoms, functional status both physical and emotional, as well as satisfaction and social functioning in work, leisure, social life, family, and sexual activity (40).

There are different tools to measure HRQoL, here we have the two main available approaches (41).

- **Generic instruments**: which aim to be comprehensive and cover a huge range of life domains and apply to many illness groups:
  - ➔ **Health profiles** are single instruments that measure several separate aspects of the quality of life.
  - ➔ **Utility measures** involve the patient estimating her QoL along a continuum from death to full health.
- **Specific instruments** focus on symptoms and problems that are specific to a single medical condition or assess a particular body function.

In our study, we are using a generic instrument since our patients suffer from a variety of different conditions included in acute coronary syndromes.

We choose to use short-form 26 (SF-36) as it appears to be the most reliable, valid, and sensitive assessment of the quality of life (41), and it is the one used at *Santa Caterina's hospital,* so it is the most accurate way of assessing our main outcome variable, as our population is from the city of Girona.

5. JUSTIFICATION

CR is a multidisciplinary programme of preventive measures for risk reduction and global long-term care of the cardiac patient. It is a class IA recommendation in evidence-based guidelines, and it is highly cost-effective.

Although referral to CR is designated as a performance measure of healthcare quality after AMI, CR has failed to reach >80% of eligible women in the last 3 decades. **Women are referred to CR 32% less than men, they attend 36% less, and of those who do attend, 27% do not complete the program**. Interventions for increasing CR referral, enrolment, and adherence of women are insufficient, though the clinical outcome is at least as great in women as in men (16).

One recent randomized controlled trial examined the effects of an enhanced CRP for women and found that it significantly improved quality of life and depressive symptoms compared with traditional CR. That is why we believe that a HBCRP based on the ***Aula Abierta de Rehabilitación Cardiaca*** materials will be an effective and realistic, novel, and adaptative option for women with significant barriers to attending structured outpatient programs. It is also free of charge, available 24 hours a day, 365 days a year (8,37). It takes a particular usefulness in the Covid-19 pandemic reality that we are living.

With our study, **we aim to provide more evidence to secondary prevention models** that are culturally sensitive and personalized to women's psychosocial and physiological characteristics. More research is needed, as home-based programmes are currently considered a Class IIa recommendation, and telemedicine, class IIb (18).

We will also address the treatment-risk paradox, as we will focus also on women with reduced functional capacity, depression, or both, as they are at higher risk for underuse of beneficial CR, so we will try to improve this situation using *AARC* in our HBCRP (19).

Home-based versus centre-based forms of cardiac rehabilitation are equally effective for improving HRQoL outcomes in low-risk patients after MI. Thus, the choice of participating in one or the other should reflect the preference of the individual patient. However, we want to provide data to help confirm it, specifically in women, as they are a suboptimal assessed group (21).

We will design a randomized controlled trial to test the positive effects of HBCRP in a women sample, **studied less so far**. This will allow us to test the previous results to individuals who typically have not been subjects of CRP trials.

In conclusion, the sample of our study allows us to test **whether this treatment improves the health-related quality of life (HRQoL) for all women patients after an ACS**.

Regarding the outcomes, we analyse the health-related quality of life as the aim of CR is, by definition, to restore the patients to the optimal physical, psychological, economic, and social status (WHO 1993), which in other words is defined as quality of life. We want better outcomes by giving solutions to the barriers to the completion of CR programs in women, so they can also benefit from it. The quality-of-life measurement is, therefore, needed to demonstrate program-mediated chances of improving psychosocial and social well-being of the patients in an effort to determine effective and efficient rehabilitation strategies (22) .

Finally, the setting of **Girona** and *Hospital Universitari Doctor Josep Trueta (HUDJT)* has sufficient sample and a CR programme in *Hospital de Santa Caterina*, which we think could see its adhesion reinforced, as in women population it has been much lower than in its male counterparts.

6. HYPOTHESIS

6.1 Main hypothesis

- *Aula de rehabilitación cardiaca* home-based telematic cardiac rehabilitation program in addition to current cardiac rehabilitation programs improves the quality of life in women with acute myocardial infarction.

6.2 Secondary hypotheses

The secondary hypotheses of this protocol are the following:

- *Aula de rehabilitación cardiaca* home-based telematic cardiac rehabilitation program in addition to current cardiac rehabilitation programs has a lower occurrence of anxiety and depression symptoms.
- *Aula de rehabilitación cardiaca* home-based telematic cardiac rehabilitation program in addition to current cardiac rehabilitation programs has lower drop-out rates when compared to centre-based CRP alone.

7. OBJECTIVES

7.1 Main objective

- To measure if the use of *Aula de rehabilitación cardiaca,* a home-based telematic cardiac rehabilitation program, in addition to current cardiac rehabilitation programs in women who had a myocardial infarction has better outcomes in terms of health-related quality of life *measured at 6, 12 and 24 months*.

7.2 Secondary objectives

- To identify if there are differences related to anxiety and depressive symptoms between both groups (using the State-trait anxiety inventory (STAI) and the Zung self-rating depression scale, both validated), reporting if there are lower rates of the mentioned symptoms in the home-based telematic cardiac rehabilitation group using AulaRC, *measured at 6, 12 and 24 months*.
- To measure compare the drop-out rates from both groups and see if there is a lower drop-out rate in the intervention group.
- To assess the rate of quitting smoking because of the intervention, registering who quits in each group and *assessing it again at 6 and 12 months* to see if they become former smokers.

8. METHODOLOGY

8.1 STUDY DESIGN

We will design a controlled and randomized clinical trial.

The patients will know whether they are doing telematic home-based rehabilitation apart from the current one offered by actual guidelines. Therefore, according to the characteristics of the intervention, it will be impossible to conduct a blind study.

The methodology that we will follow consists of randomly assigning to half of the recruited patients the CR with the HBCRP and standard CR currently provided by centres in our health system to the other half.

The patient's quality of life and anxiety and depression symptoms will be appraised using written questionnaires (SF-36, STAI and Zung).

8.2 POPULATION OF INTEREST

All the participants are of those looked after in *HUDJT.*

8.2.1 Inclusion criteria

- All adult women who have suffered from myocardial infarction or unstable angina but have been medically or surgically treated and are currently clinically stable.
- All patients must have signed the informed consent.
- All women must undertake a cardiac stress test before CRP plus AulaRC.

8.2.2 Exclusion criteria

- Patients with CHD in the acute phase, with signs and symptoms of unstable angina or currently with angina induced by effort.
- Patients who are unable to understand the language of our study or remember instructions.
- Patients who have a contraindication for physical exercise.
- Patients who have no access to the internet connection at home or through mobile phones.

8.2.3 Withdrawal criteria

- Patients unwilling to attend the program or who revoke the informed consent.
- Patients not attending sessions continually will be considered as abandonment and will be excluded from the study.
- Presence of clinical or surgical complications that don't allow the patient to continue in the study.
- Delayed identification of a violation of the inclusion and/or exclusion criteria.

8.3 SAMPLE CALCULATION AND SAMPLING METHOD

8.3.1 Sample size

In this study, we will compare two independent means: the mean of HRQoL of patients who attended a HBCRP plus the current CRP compared to the mean of HRQoL of patients who did CRP alone.

In a bilateral test, with an alpha equal to 5%, statistical power equal to 20%, and assuming a statistically significant result (22), the number of subjects in each arm will be 87. However, assuming a dropout rate of 20%, the number of subjects results in 104 in each arm.

Computations were carried out based on the package 'pwr' (45).

8.3.2 Methods of recruitment and randomization

From the clinical experience of the Cardiology service in the *HUDJT* we have concluded that we need around 1 years to get a sample of 208 women patients with ACS.

For a period of 1 year, as patients who meet the inclusion criteria get diagnosed, they will be offered the option of entering the trial. Thus, we will carry out a consecutive non-probabilistic sampling method in the centre *HUDJT* including all the patients meeting the inclusion and exclusion criteria.

To be able to start the intervention with a group of patients, we will conduct a recruitment during two months of patients from the Cardiology service with these conditions. This two-month period is for a good number of participants to start together the AulaRC use and weekly videoconferences with cardiologists. Inpatients of the hospital between February 2022 and April 2022 who meet the inclusion criteria will be offered to enter the trial.

From then on, from a period of one-year, enrolled patients are randomly assigned at a 1:1 ratio in two groups: an *intervention group* which joins AulaRC HBCRP and a *control group* that does not. The randomization process is conducted by the main investigator. Each patient will be assigned an identification number obtained by a number code generator to keep anonymity using a method of sealed envelopes (as Sealed Envelope Ltd.).

Patients who don't want to be randomly chosen are not allowed to participate in the study. Nevertheless, these patients are still allowed to follow a HBCRP using AulaRC, but they will not be part of our analysis since data could potentially suffer from self-selection bias.

Furthermore, every patient will receive an information sheet together with the informed consent and the recruitment questionnaire. All this will be read, understood, and completed by the patient with the doctor's help and handed to the main investigator.

8.3.3 Masking techniques

This study is designed as an open-labelled clinical trial, because of the unfeasibility of blinding the personnel in charge to instruct the CRP. It is neither possible to mask the intervention to the patient, who will know whether they are receiving the rehabilitation online program or not. To reduce possible bias, what we will guarantee is the blinding of the researcher in charge to apply the quality-of-life questionnaires, Zung and STAI questionnaires, and the measure of the drop-out rates, not knowing to which group each participant belongs to.

8.4 VARIABLES

INDEPENDENT VARIABLE*:*

To join Aula de RC home-based telematic cardiac rehabilitation program. This is a qualitative nominal dichotomous categorical variable since it has only two categories: to be included in a HBCRP or not.

DEPENDENT VARIABLE:

Main outcome:

- *Patient's quality of life*:
  This is a quantitative discrete variable since the SF-36 quality of life questionnaire can only take values based on a count from a set of distinct whole values.

Secondary outcomes:

- *Level of anxiety and depression symptoms*:
  Both variables will be measured by the scores Zung self-rating scale for depression and State-trait anxiety inventory for anxiety, and therefore they are discrete variables.

- *Drop-out rates:*
  This is a qualitative nominal dichotomous variable.

- *Quitting smoking rates:*
  This is a qualitative nominal dichotomous variable.

COVARIATES:

- *Age* – it is a quantitative continuous variable that will be expressed in years.
- *Basal level of anxiety and depression symptoms* – it is a discrete variable.
- *Level of comorbidity (using Charlson Comorbidity Index)* – it is a discrete variable.
- *Obesity (BMI>=30 kg/m^2)* – it is a qualitative nominal dichotomous variable.
- *Smoking* – it consists of a qualitative nominal dichotomous variable.
- *Socioeconomic level*, approached by occupation and education – it is a qualitative polytomous variable.

The type of variables and covariates together with their measurement unit can be seen in table 4 as it follows:

Table 4. Variables assigned in the clinical trial

	VARIABLE	TYPE	CATEGORIES
INDEPENDENT VARIABLE	To join AulaRC	Qualitative nominal dichotomous	Yes / No
MAIN OUTCOME	Quality of life	Quantitative discrete	0-100
SECONDARY OUTCOME	Level of anxiety and depression symptoms	Quantitative discrete	0-120 (STAI) 20-80 (Zung)
	Drop-out rates	Qualitative nominal dichotomous	Yes / No
COVARIATES	Age	Quantitative continuous	
	Basal level of anxiety and depression symptoms	Quantitative discrete	0-120 (STAI) 20-80 (Zung)
	Comorbidity	Quantitative discrete	1-7
	Obesity	Qualitative nominal dichotomous	Yes/No
	Smoking	Qualitative nominal dichotomous	Yes / No
	Socioeconomic level	Qualitative polytomous	Social Class I, I, III, IV, V (Social Class V as the lowest socioeconomic level)

8.5 SAFETY

All the interventions of this study are being performed on the current clinical basis on the hospitals participating in the study (*HUDJT* and *Hospital de Santa Caterina*), except the implementation of at-home use of the Aula de rehabilitación cardiaca online platform.

The use of the platform and the execution of the activities proposed in the videos does not involve any added risk to the patient, as no complications derived from it neither from the assessment nor the outcomes of this study, demonstrating its safety and feasibility.

8.6 STUDY INTERVENTION: Aula Abierta de Rehabilitación Cardiaca

As we have been stating, after the patients are informed about the trial (Annex IV) and sign the consent to become a participant (Annex V), they are randomly assigned in the two explained groups

All patients in both groups must go through a **pre-evaluation** that includes:

- **Cardiac stress test**: To ensure security, we assure patients will not exercise to a higher cardiac frequency of 75-80% of her maximum and we must know and assess other risks (arrhythmias or inadequate responses to PE).
- **Recruitment questionnaire** (Annex VI) to get age, basal diagnosis, and Charlson comorbidity Index of our patients (Annex VII).
- **Filling up the SF-36 test** (Annex VIII)
- **Filling up the Zung test** (Annex IX)
- **Filling up the STAI test** (Annex X)

The CPR consisting of the phases explained previously will start for all patients in both groups, but we will also start the use of AulaRC for those patients assigned to participate in it.

For the intervention group we will divide between *inpatient* and *outpatient* as the following:

PHASE 1:

Education and counselling will start as *inpatients* as we will explain what AulaRC is as well as the early mobilization, standing from the bed and doing arm movements, supervised by the responsible doctor. Before the hospital discharge, patients will learn how to create a user in the AulaRC platform and will watch the first 3 videos consisting of: "Why do cardiac rehabilitation", "What is cardiac rehabilitation", and *Presentation of the AulaRC platform*: "Objectives and functioning".

PHASE 2:

In the *outpatient* phase, we will start the current CRP programs and we will cite the patients with a prescription paper to go to the CRP centre-based programs in *Hospital de Santa Caterina* to all patients in our study and, in addition, we will follow with the use of AulaRC in the intervention patients as they will have to do what we explain in the page below. Our intervention will last 24 weeks (six months).

- First, they will have to watch the **other videos in the *Presentation of the AulaRC platform*** section: "Measurement of pulse and heart rate, use of the pulsometer and measurement of blood pressure", "Learning of Borg sensation", and "Learning of alarm symptoms to consult"
- Second, they will do **two days a week of the *training programme* with the videos**: "Importance of exercise in heart disease", 2 videos of "Adapted home aerobic activity and strength" and two videos of "Suggested out-of-home aerobic activity and strength". The **first week** they will watch the first one ("Importance of exercise") and will perform the PE in one of the "Adapted home aerobic activity and strength".
- Third, they will watch **weekly a video from the educational section** as "How the heart works" and each week they will watch one of the 11 videos on diseases they suffer, the risk factors, and the importance of treatment adherence. The subjects of the 24 talks that will take place during the whole program are defined in the AulaRC, and as there are 11 subjects, they will watch each video twice, and the last two weeks we will do an online meeting discussing other educational subjects in groups, individualizing for the interests of every patient.
- Finally, they will watch **weekly a video from the psychological section**. As there are 5 videos about emotions, relaxation techniques, and how to handle stress, they will watch a video weekly doing it for 4 times, during the first 20 weeks. For the last 4 weeks we will do an online meeting weekly trying other techniques in groups, as the Jakobson progressive muscular relaxation audio guided.

For every video, there is a questionnaire that must be filled up on the webpage after watching it so they can see what they have learned and get positive feedback. They will have to do these tests after every video.

In addition**, once at the beginning of the week** on Monday we will have an **online meeting videoconference through Zoom** with 5 groups of about 20 patients, that will discuss how they have seen themselves using the platform that past week. Five cardiologists will oversee these meetings and will engage the patients in next week's exercises as well as solve their doubts.

In conclusion, during phase 2, we will follow **the patient exercises progression** controlled and registered through a sheet of paper using the *Borg scale* of perceived exertion.

PHASE 3

Six months after starting the trial both the intervention and control group will fill up the *SF-36, Zung, and STAI tests* again. This way we assess the short-term effects in **post-program evaluation.**

PHASE 4

This phase corresponds to the permanent and not supervised PE the patients must do after CRP with AulaRC has finished. It consists of 30 minutes of moderate PE per day, as trained in the centre-based CR. They can continue, and we will recommend so, to use the platform, as we will provide skilful means to increase long-term motivation.

PHASE 5:

- **PATIENT'S FOLLOW-UP**

We want to assess the patient's HRQoL, depression, and anxiety symptoms for a period of two years since the beginning of the study to see if changes in HRQoL and depression and anxiety symptoms last for this period.

All patients will fill up the SF-36, Zung, and STAI questionnaires **one and two years** after the trial starts.

FIGURE 8. *Overall view of the different indexes in AulaRC with its programs and videos about physical exercise and psychological therapy*.

8.7 DATA COLLECTION

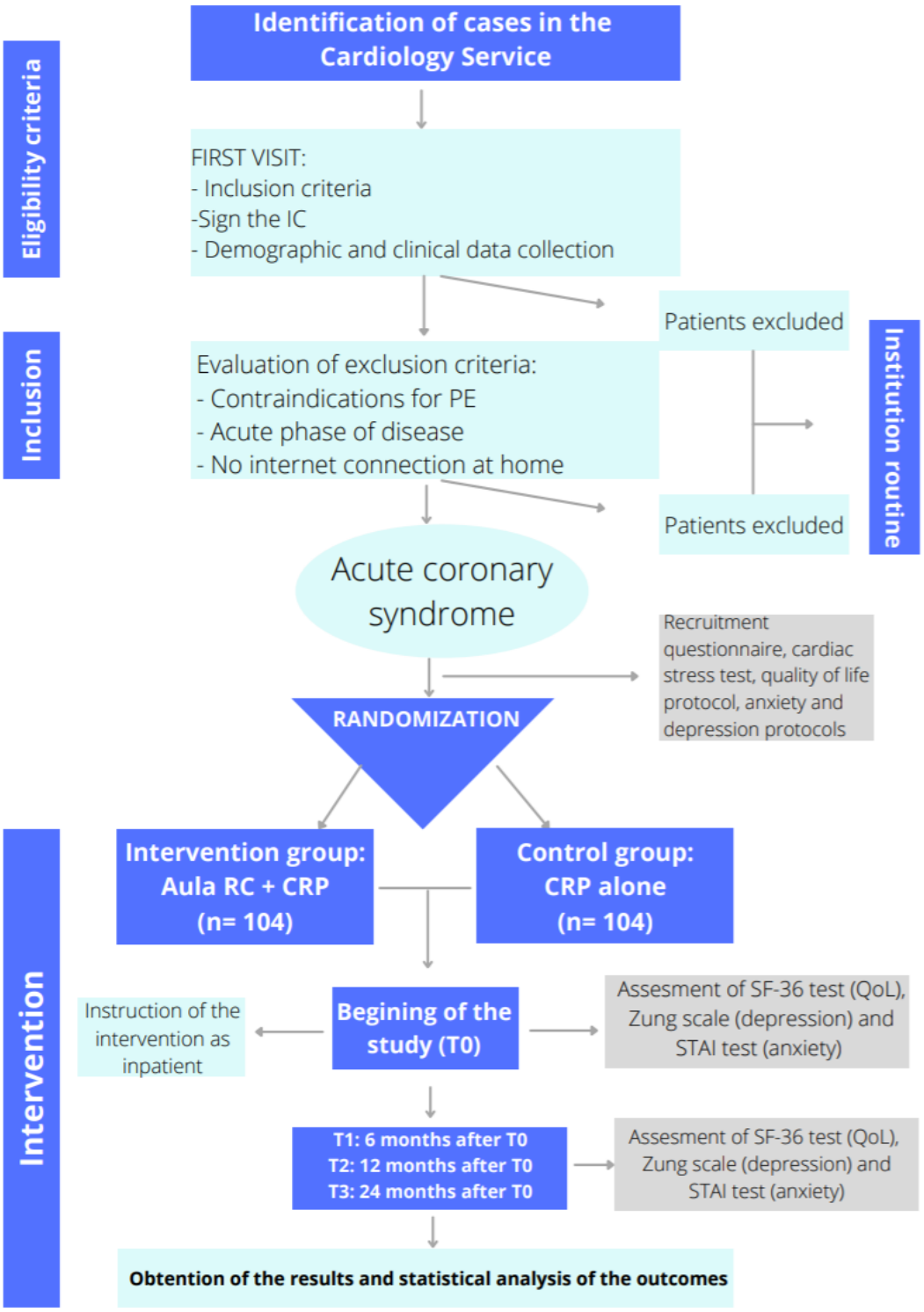

FIGURE 9. *Data collection flow diagram.*

8.8 MEASURE INSTRUMENTS

In our study, we are using a generic instrument since our patients suffer from a variety of different conditions included in acute coronary syndromes.

We choose to use short-form 26 (SF-36) as it appears to be the most reliable, valid, and sensitive assessment of the quality of life (41), and it is the one used at *Santa Caterina's hospital,* so it is the most accurate way of assessing our main outcome variable, as our population is from the city of Girona.

8.8.1 The Short Form 36

The SF-36 is a generic multidimensional instrument consisting of eight items:

1. **Physical functioning**: is measures the extent to which health limits physical activities such as self-care, walking, or climbing stairs.
2. **Role functioning physical**: it measures the extent to which physical health interferes with work or other daily activities.
3. **Bodily pain**: is measures the intensity of pain and the effect of pain on normal work.
4. **General health perception**: including personal evaluation of current health and resistance to illness
5. **Vitality**: referring to the feeling of being full of energy rather than tired and worn out.
6. **Social functioning**: the extent to which physical health or emotional problems interfere with normal social activities.
7. **Role functioning emotional**: the extent to which emotional problems interfere with work or daily activities.
8. **Mental health**: it measures general mental health including depression, anxiety, behavioural-emotional control, and general positive affect.

Each of these scales has a possible range of scores of 0-100 and a high score indicates a better health state. To calculate the QoL score for every item, it is necessary to first homogenize the direction of the answers, so all items follow the rule "higher punctuation, better health state", then to sum the different items of the scale and finally to do a linear transformation to obtain numbers between 0 and 100 for every scale (42).

In this study the dependent variable is the aggregate outcome of all the different aspects, this is calculated through the mean of these eight items.

8.8.2 The Zung Self-Rating Depression Scale

The Zung scale is designed to assess the level of depression in each patient as self-perception. The test consists of the patient **answering 20 questions about how she has been feeling in the last week**. On the same sheet are the affiliation data and then the columns indicating the 4 possible answers. There are positive symptoms, which describe depression, and negative symptoms, which are the opposite. To evaluate it we will put the answers into the score table, remembering that the positive ones go from 1 to 4 and the negative ones from 4 to 1.

Finally, we will interpret the results according to the score as: within normal limits, mild-moderate, moderate-severe, or severe depression (43).

8.8.3 The State-Trait Anxiety Inventory (STAI)

The STAI is a questionnaire that **consists of 40 questions to be answered by the patient in which she will indicate how anxious she feels in various situations**. The main purpose of this scale is to find out how much anxiety the patient suffers but differentiate whether this anxiety is something characteristic of the patient (trait) or if it is something momentary, in response to a stressful event (state). High scores on the questionnaire are associated with higher levels of anxiety. It has two scales, each with 20 items. The items are answered from 0 to 3. Then, we will use the specific punctuation for women that has the following categories: very high, medium-high, average, medium-low, and very low (44).

We decided to use both Zung scale and STAI because these are the ones used in *Santa Caterina's hospital*, the reference hospital for centre-based cardiac rehabilitation programs in the province of Girona.

8.8.4 Dropout rates

The dropout rates will be assessed through the registration of dropouts in both groups during the 6 months of the study. In the end, we will calculate the percentages of dropouts in each group as the dropout rate.

8.8.5 Smoking quitting rates

The quitting rates will be assessed in the same way used in dropout rates.

9. STATISTICAL ANALYSIS

9.1 Descriptive analyses

The drop-out and smoking quitting rates (qualitative nominal dichotomous) and the *Patient's quality of life* and *Level of anxiety and depression symptoms (discrete variables*) will be summarized using the **n (%)** for the first two, and **median and the interquartile range** for the last two.

These analyses will be stratified by the intervention (*To join AulaRC home-based telematic cardiac rehabilitation program*).

Furthermore, the analyses, already stratified by the intervention, will be additionally stratified by the covariables. Quantitative covariables will be categorized in quartiles.

9.2 Bivariate Inference

The difference of drop-out and smoking quitting rates between AulaRC group and no-AulaRC group will be assessed by means of the **chi-squared test**.

In the case of the medians of quality of life and the level of anxiety and depression between AulaRC group and no-AulaRc group, differences will be assessed by means of the **Student's t-test**, which is a parametric test that assumes the variables to be normally distributed. We will contrast these results to those obtained by the **Mann-Whitney test**, which drops the normality assumption.

These analyses will be additionally stratified by the covariables. Quantitative covariables will be categorized in quartiles.

9.3 Multivariate Analyses

In the assessment of the effects of the intervention on the quality of life and level of anxiety and depression, for all the confounding factors that could show significant statistical difference, we will adjust the associations between the AulaRC effect on the QoL for the confounding covariates such as age, comorbidity, smoking, and socioeconomic level. This adjustment will be performed using logistic regression analysis.

For drop-out and smoking quitting rates linear regressions will be used. Again, controlling for the covariables.

10. ETHICAL ASPECTS

This trial will be carried out according to human rights and the ethical principles for medical research described by the *Helsinki Declaration of Ethical Principles for Medical Research Involving Human Subjects*, established in 1964 and last revised in October 2013.

All patients will be properly informed of the trial's objectives and interventions before joining the trial. It is imperative that they read and understand the information before they are asked to sign the informed consent. Their autonomy will be always respected.

Participant's information will be confidential, guaranteeing anonymity, in accordance with:

- *Reglament (UE) 2016/679 del Parlament i del Consell Europeu, de 27 d'abril de 2016, relatiu a la protecció de les persones físiques en quant al tractament de dades personals i a la lliure circulación d'aquestes dades.*
- *Llei Orgànica3/2018, de 5 de desembre, de Protecció de Dades Personals i Garantia dels Drets Digitals (LOPD-GDD), en especial en la seva Disposició Addicional 17.2.*

The study has been presented to the **"Comitè d'Ètica de l'Hospital Universitari Doctor Josep Trueta"** to be evaluated and is now pending approval.

We declare no conflict of interest of any kind.

11. LIMITATIONS

The main limitation in our opinion is that this is an open label trial: patients know whether they are doing AulaRC's activities or not. In the same way, recruitment process might be another problem since it is possible that many patients refuse to be randomly assigned because they prefer either to take AulaRC's activities or not. If this meant a real problem during the study, we would consider not offering the option of joining AulaRC it is not as a part of the study and according to randomization. In addition, as we are doing a consecutive non-probabilistic sampling method, we could potentially suffer from selection bias. However, this bias will be minimized in the multivariate analysis.

We can also suffer from volunteer bias, as the patients who accept to join the trial could be more committed to it and therefore, we could get a lower improve in QoL due to the intervention than expected.

A third evident limitation is that we cannot warrantee our results can be extrapolated to other regions or countries. We cannot extrapolate the results to men population neither, as we have a women-only sample. Nevertheless, randomization of patients and using validated questionnaires increases reliability to extrapolate outcomes to other populations. Furthermore, in relation to the non-inclusion of men, we believe that the motive and justification for the study, as well as the current theoretical framework, makes the decision taken by the researcher appropriate.

Another limitation might be the need of having access to internet connection through some device at home, as elderly women or women in a very low socioeconomic status may not have it and thus, they would be excluded from the study. Therefore, we stress the importance of the involvement of family members.

Since we are assessing the QoL, but controlling its changes only for two years, another limitation could be the reduced following up of patients. This might be a valid objective for future studies: to find the way of having a longer effect on the better quality of life of the patients.

In addition, we have to be aware that QoL, and depression and anxiety symptoms, can easily be affected by many uncontrollable factors, for example, season changes affect tiredness and capability of exercising and personal and family problems affect emotional status. We aim on following our patients over a period of two years and we use validated questionnaires to minimize these confusions factors, but we have to be aware these could still affect our data.

Another important limitation of this study is the fact that many of these conditions progress over time and can considerably deteriorate the patient's state, this could be a confusion variable. In the same direction loss of follow-up may be a limitation since most of our patients are old and can become unable to exercise or die.

A certain information bias could happen since our main variable outcomes are assessed using questionnaires. However, all of them are validated and the women will be sufficiently committed with the study, being provided with an information sheet, and signing the informed consent.

Finally, our estimations conclude that we need around one year to obtain 208 patients with the mentioned characteristics in the population covered by *HUDJT*. In the case this was not possible or with the intention of reducing the recruitment period we could consider a multicentre study. The problem in this case would be the higher variability of the approaches, the more difficult organization, and the higher costs.

12. WORK PLAN AND CHRONOGRAM

The activities developed in the clinical trial will be organized in the following phases:

STAGE 0: STUDY DESIGN, PREPARATION AND COORDINATION (*3 months: February 2022 – April 2022*) COMPLETED.

1st step: a protocol of the study will be designed by the main investigator, starting with bibliographic research, the aim of the study and the main hypothesis. The approach of the *HUDJT* will also be performed. This step is subject to modification by input from the court.

2nd step: the study protocol will be developed, containing a detailed explanation of the variables and objectives proposed for the study, and the analytical framework establishment. A project manager will be hired to manage the patient's information, control the collection of the variables, ensure the compliance of timelines and responsible of a correct communication between all the professionals collaborating.

3rd step: the entire team will meet to specify everyone's task and create the chronogram in collaboration (available in the page below the end of the work plan). The researchers will meet regularly during these three months and during the whole period in order to control and assess the progression of the trial.

STAGE 1: ETHICAL APPROVAL (*2 months: April 2022 – May 2022*)

3rd step: protocol will be presented to the *Comitè Ètic d'Investigació Clínica (CEIC) of HUDJT* for its revision and approval. All suggested changes will be considered.

STAGE 2: FIELD RESEARCH AND DATA COLLECTION (*3 years: June 2022 – June 2025*)

4th step: we will perform the **sample collection**, patients meeting the inclusion and exclusion criteria who come to HUDJT and are willing to take part in the study will be invited to sign the informed consent and join the trial (Annex IV-V). First, we will do a two-months recruitment, and then, a continuous recruitment until the end of one year.

5th step: we will start the **intervention**. Patients in the control group will receive standard CRP provided by the health system at *Hospital Santa Caterina.* Patients in the intervention group will take a cardiac stress test and start the six months Aula RC use plus CRP.

6th step: patients will fill up the **quality of life, anxiety, and depression questionnaires**. All patients must fill up the SF-36, Zung, and STAI questionnaires in four occasions: in the *Week 1*, in the *Week 24* (right after the program has finished for the patients in the intervention group), in the *Week 48* (one year), and in the *Week 96* of the start of the program (two years).

STAGE 3: DATA COLLECTED ANALYSIS (*3 months: June 2025 – August 2025*)

7th step: statistical analysis will be performed by a masked statistician at the end of the study when all the data has been collected. Each patient will be given a number that will include all her information in order to ensure confidentiality. Quality controls will be carried out.

STAGE 4: FINAL REPORT PHASE (*4 months: September 2025 – December 2025*)

8th step: there will be a last meeting where the investigators will discuss and analyse the data collected. Final discussion of the clinical trial will be elaborated by all the group, generating a final report showing the study results and conclusions.

STAGE 5: PUBLICATION AND DISSEMINATION PHASE (*6 months: January 2026 – June 2026*)

9th step: findings of the clinical trial will be published on different scientific journal articles, reports, and conference presentations.

10th step: final report will be presented to the Sociedad Española de Cardiología (SEC), and to the European Society of Cardiology (ESC).

TASKS	2022								2023							2024						2025										2026					
	Feb	Apr	May	Jun	Jul	Aug	Sep Oct	Nov Dec	Jan Feb	Mar Apr	May Jun	Jul	Aug	Sep Oct	Nov Dec	Jan Feb	Mar Apr	May Jun	Jul Aug	Sep Oct	Nov Dec	Jan Feb	Mar Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun
0. STUDY DESIGN, PREPARATION AND COORDINATION																																				
Protocol elaboration and evaluation																																				
Coordination of research team																																				
1. ETHICAL APPROVAL																																				
Presentation and approval																																				
2. RECRUITMENT, FIELD RESEARCH AND DATA COLLECTION																																				
Two-month recruitment																																				
Continuous recruitment																																				
AulaRC cardiac rehabilitation program																																				
3. DATA COLLECTION AND ANALYSIS																																				
Data collection and analysis																																				
Quality assurance control																																				
4. FINAL REPORT PHASE																																				
Interpretation and final report																																				
5. PUBLICATION AND DISSEMINATION PHASE																																				
Publication of the article																																				
Conferences and congresses																																				

13. BUDGET

To calculate the needed budget for this trial we have divided the costs in human needs, material, and publication costs.

AulaRC is an online cardiac rehabilitation programme that is an open classroom, free of charge, available 24 hours a day, 365 days a year for training, self-care, and exercise from home even in times of confinement. Because of that, we will be using a free of cost intervention as long as the patients have access to the internet. The CRP, carried out at Santa Caterina's hospital by both intervention (AulaRC plus CRP) and control groups (only CRP), is also covered by the health care system and will thus, it does not add an extra expense.

We need 5 cardiologists for the weekly videoconferences (1 hour a week; 144 hours in total). We need one statistician expert in charge of analysing the data, that will happen at the end of the study for about 100 hours. We also need skilled staff to carry out the data monitoring and quality control (2 hours a month; around 80 hours). Our graphic designer is working on the posters and AulaRC platform exercises booklet for a better understanding and adherence to the intervention (watching and performing the activities proposed at home). He/she will work for about 15 hours.

We ask for 36.125 € in total but we expect *El Ministerio de Sanidad y Consumo* to refund and take responsibility of 25.000 € of it. When our requests and applications go through, we will be certified to carry this Project and will not have to pay for the worker's salaries but only the inherent costs to the study (quality control, statistician, and publication costs).

Therefore, *the cost of this project is 11.125 €.*

STAFF		
5 cardiologists	144 h x 35 € / hour	5.040 €
SUBTOTAL		**25.200 €**
Statistician	100 h x 35 € / hour	3.500 €
Quality control manager	80 h x 35 € / hour	2.800 €
Graphic designer	15 h x 35 € / hour	525 €
MATERIAL		
Printing and papers		100 €
PUBLICATION AND DISSEMINATION		
Publication costs		2.000 €
Congress costs (registration, travelling, accommodation)		2.000 €
TOTAL		**36.125 €**

14. FEASIBILITY AND IMPACT ON THE HEALTH SYSTEM

- **FEASIBILITY**

This clinical trial will take place in *the Josep Trueta Hospital*. Concerning why we chose it, believe that there is *sufficient sample*, according to the incidence of myocardial infarction in women per year, data provided by the Cardiology service. With the size sample (208 patients), we expect that in one year all the patients will be recruited, as there are approximately 200 cases of AMI in the hospital, according to administration data of HUDJT.

We also believe that it would facilitate adherence to the CRP, which in the city of Girona are only carried out in the other main hospital, the Santa Caterina.

The medical team required for this study is composed of 5 cardiologists that will be in charge of the videoconferences for assessing the progresses made with AulaRC. All these professionals already belong to the hospital team and will collaborate in the study as *they have vast experience in the field.*

Consequently, we consider it is possible to develop this clinical trial and it can benefit many patients in the long run.

- **IMPACT ON THE NATIONAL HEALTH SYSTEM**

Nowadays IHD and ACS are the first cause of morbimortality all around the world. Their complications and recurrences can be eased and delayed when using secondary prevention strategies. Women historically and have suffered from a lack of resources and several barriers to access cardiac rehabilitation, a class IA recommendation in guidelines when compared to men. There is a gap in research for finding solutions for the lower referral, attention, and completion of the CRP in women.

The results of this trial could bring additional data to the existent knowledge about different options and types of CR, giving more flexible and easier ways to access CR as well as empathizing more with the experience of having a myocardial infarction in women.

If the presented hypothesis is confirmed and is proven that adding AulaRC use to current CRP is easy and effective, patients will benefit from the implementation of it on their daily basis and their quality-of-life as well as their depression and anxiety symptoms will get better.

15. PUBLIC AWARENESS-RAISING

As we have been discussing, the awareness of ischaemic heart disease must be reassured amongst our population, and we hope the study will help improve adherence to both pharmacological and non-pharmacological treatments after an AMI.

Moreover, using **educational resources** about cardiac rehabilitation in its different options we hope the family will involve themselves in the treatment, which is life-long.

We will therefore launch a **campaign** to publicise the study and what we are going to do and what it consists of. We will put up **posters** explaining myocardial infarction in women and cardiac rehabilitation (Annex XI). We would like to explain our initiative to TV Girona as well, we think it would have a very positive impact. Finally, Elena from Scarlatta shop, an influencer businesswoman, that runs a famous store in the centre of Girona, has already agreed to talk about our trial on her social media, were she has more than 40 000 followers, of which 90% are women.

In conclusion, we think it is important for the population to get involved and get to know about the study.

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17. ANNEXES

Annex I: CLASSES OF RECOMMENDATION AND LEVELS OF EVIDENCE

CLASSES OF RECOMMENDATION AND LEVELS OF EVIDENCE

CLASSES OF RECOMMENDATION	
Class I	Evidence and/or general agreement that a given treatment or procedure is beneficial, useful, effective. It is recommended/ it is indicated
Class II	Conflicting evidence and/or divergence or opinions about the usefulness/efficacy of the given treatment or procedure
Class IIa	Weight of evidence/opinion is in favour of usefulness/efficacy. Should be considered
Class IIb	Usefulness/efficacy is less well established by evidence/opinion. May be considered
Class III	Evidence or general agreement that the given treatment or procedure is not useful/effective and in some cases may be harmful

LEVELS OF EVIDENCE	
Level A	Data derived from multiple randomized clinical trial or meta-analyses
Level B	Data derived from a single randomized clinical trial or large non-randomized studies
Level C	Consensus of the experts and/or small studies, retrospective studies, registries

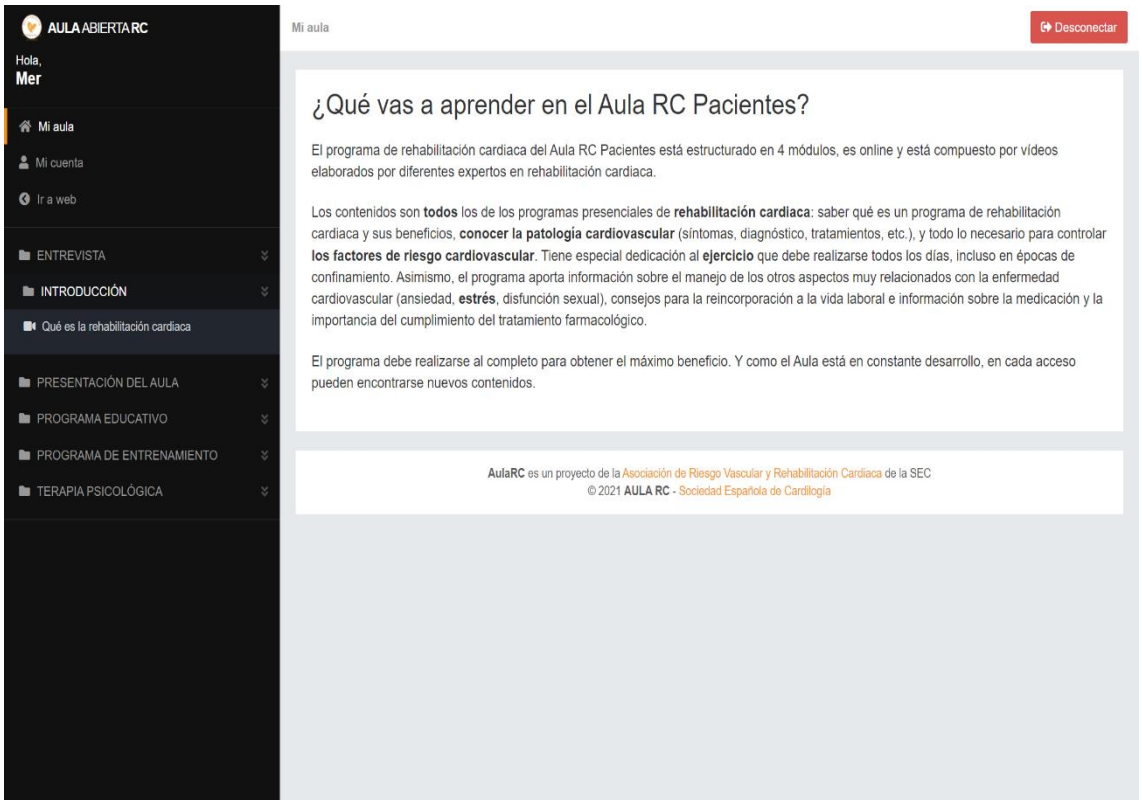
Annex II: THE BORG SCALE

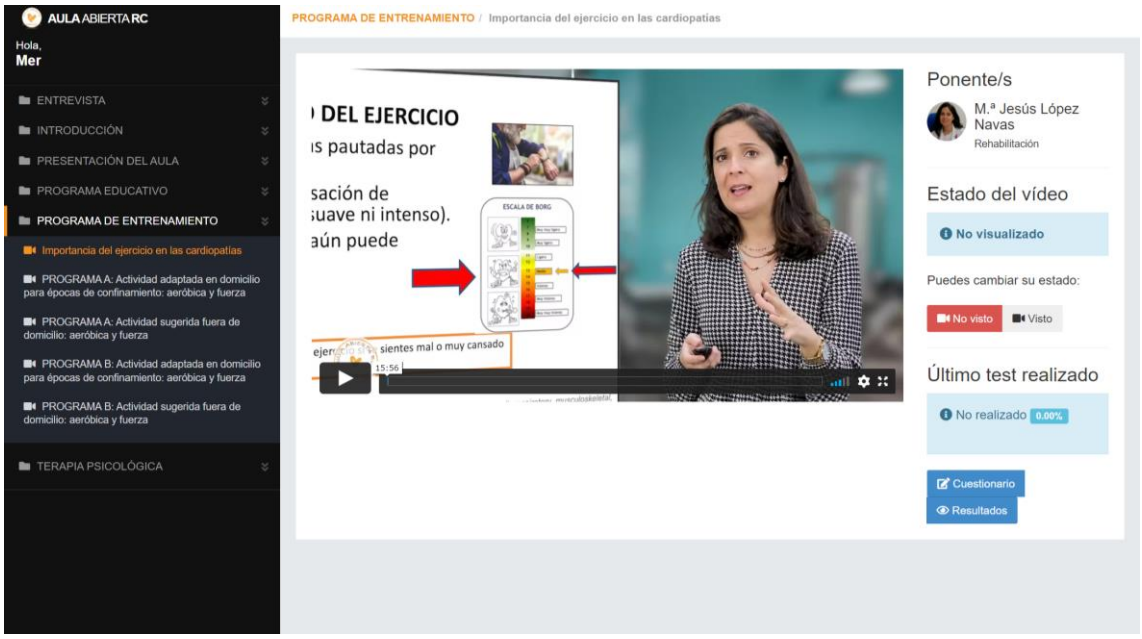
THE BORG SCALE

	DESCRIPCIÓ
0	**Repòs total.** Inactiu.
1	**Esforç molt suau.**
2	**Suau.** *Warm-up* i estiraments.
3	**Esforç moderat.** Respiració i cor accelerats.
4	**Una mica dur.**
5-6	**Dur.** Respiració intensa, difícil mantenir una conversació.
7-8	**Molt dur.**
9	**Massa dur.** Impossible parlar.
10	**Esforç màxim.** Impossible de mantenir

Annex III: EXAMPLE OF CONTENT IN AULARC WEBSITE

EXAMPLE OF CONTENT IN AULARC WEBSITE





Annex IV: PARTICIPANT'S INFORMATION SHEET

FULL D'INFORMACIÓ AL PACIENT

Projecte:

AULA DE REHABILITACIÓN CARDIACA USE IN WOMEN AFTER AN ACUTE CORONARY SYNDROME IMPROVES THEIR QUALITY OF LIFE

Vostè ha estat convidat a participar en un estudi clínic sobre rehabilitació cardíaca telemàtica.

Per favor, prengui el seu temps per a llegir aquesta informació. Es important que la comprengui i faci qualsevol pregunta al respecte. Quan hagi llegit aquest document, i si hi està d'acord, haurà de prosseguir amb el consentiment informat I el qüestionari necessari per a entrar en l'estudi.

Moltes gràcies.

El propòsit d'aquest estudi es veure l'efectivitat en millorar la qualitat de vida després d'afegir activitats online de rehabilitació cardíaca al programa de rehabilitació cardíaca de l'Hospital Santa Caterina per als pacients amb indicació per a ella.

Les intervencions d'aquest estudi són dues: la meitat de les pacient seran assignades a un programa de rehabilitació en l'Hospital Santa Caterina, i l'altre meitat, a més, seguirà un programa de 6 mesos realitzant activitats I vídeos de la Plataforma online Aula Abierta de Rehabilitación Cardiaca.

Les participants seran assignades aleatòriament en un grup o l'altre, com és habitual fer-ho en aquest tipus d'estudi, ja que volem comparar l'efectivitat de la intervenció, i per fer-ho així, no es controla a quin grup entra cada participant.

La duració de aquest estudi, per a vostè, es de dos anys. Esperem tenir els resultats de l'estudi complet, ja analitzats i llestos per a la publicació, al 2026.

En aquest estudi participaran 208 pacients. Per a vostè, igual que per a totes, **la participació és totalment voluntària i no remunerada**. Si vostè accepta participar en aquest, serà incorporada en un dels grups d'estudi de forma aleatòria. Vostè podrà retirar-se de l'estudi quan vulgui i sense donar explicacions, inclús si havia acceptat la participació amb anterioritat. El fet de revocar de la participació en aquest estudi, en qualsevol moment, no repercutirà en les cures mèdiques que li pertoquen per el nostre sistema de salut pública.

Les seves responsabilitats al acceptar formar part de aquest estudi són: seguir les instruccions que se li donaran a continuació, acudir al programa de rehabilitació cardíaca i realitzar les activitats per la Plataforma de internet si així se li indica, omplir i contestar els quatre qüestionaris sobre la seva pròpia qualitat de vida que se li proporcionaran en els moments indicats durant aquests dos anys i informar de qualsevol problema o dubte que li sorgeixi durant l'estudi.

La informació recollida serà estrictament confidencial. Totes les dades de caràcter personal queden introduïdes en una base de dades computeritzada per al seu anàlisis i protegides d'acord amb la legislació vigent sobre protecció de dades de caràcter personal (*Llei Orgànica3/2018, de 5 de desembre, de Protecció de Dades Personals i Garantia dels Drets Digitals).* Cap persona excepte el seu metge personal i el personal investigador podrà accedir a ells. Únicament les autoritats sanitàries podrien accedir a aquesta informació, si així ho sol·liciten.

Com a resultat de aquest estudi esperem tenir un millor coneixement de com tractar o prevenir complicacions en pacients, concretament dones, amb malaltia coronària aguda. Aquests resultats s'usaran per a la seva presentació en congressos mèdics o la publicació en revistes científiques. Podran també ser útils per al disseny de futures metodologies i possibilitats de tractament.

Pot contactar, en qualsevol moment, amb el seu metge responsable en aquest estudi i, si us plau, no dubti en fer-nos qualsevol pregunta al respecte.

Moltes gràcies.

Annex V: INFORMED CONSENT

FULL DEL CONSENTIMENT INFORMAT

Projecte:

AULA DE REHABILITACIÓN CARDIACA USE IN WOMEN AFTER AN ACUTE CORONARY SYNDROME IMPROVES THEIR QUALITY OF LIFE

Jo,……

Confirmo que:

He llegit i entès el full de informació que se m'ha entregat. He rebut suficient informació sobre l'estudi.

He pogut fer preguntes sobre l'estudi, i han estat respostes de maners satisfactòria.

He parlat amb.....

Entenc que la participació és voluntària i que puc retirar-me de l'estudi quan vulgui sense donar explicacions i sense que tingui repercussions en l'atenció mèdica que em pertoca. En conseqüència:

Dono la meva conformitat per a entrar i ser participant en aquest estudi.

Dono el meu permís al personal de l'estudi que consulti la meva història clínica, si és necessari, per a confirmar dades. També dono permís per a que totes les dades recopilades siguin utilitzades en investigacions futures.

Lloc i data:

Firma de la participant:

Document de Identitat de la participant (**DNI**):

Firma de l'investigador:

Annex VI: RECRUITMENT QUESTIONNAIRE

QÜESTIONARI PER ENTRAR A L'ESTUDI:

AULA DE REHABILITACIÓN CARDIACA USE IN WOMEN AFTER AN ACUTE CORONARY SYNDROME IMPROVES THEIR QUALITY OF LIFE

En aquest qüestionari li preguntem sobre les seves dades personals i sobre el seu estat de salut. Ompli la informació preguntada i marqui la casella correcta amb una creu quan sigui necessari.

Data de realització del qüestionari: ___ / ___ / _____ .

Nom:

Primer cognom:

Segon cognom:

Data de naixement: ___ / ___ / _____ .

El seu metge o la seva metgessa li ajudarà a omplir aquests apartats:

Diagnòstic basal: Malaltia coronària ( ) Angina inestable tractada ( )

Angina d'esforç tractada ( )

Infart de miocardi ( )

És vostè fumadora? SI ( ) NO ( )

Índex de comorbilitat de Charlson: _____

Annex VII: THE CHARLSON COMORBIDITY INDEX

SCORE	**CONDITION**
1	Myocardial infarction (history, not ECG changes only) Congestive heart failure Peripheral vascular disease (includes aortic aneurism from 6cm) Cerebrovascular disease (CVA with mild or no residual or TIA) Dementia Chronic pulmonary disease Connective tissue disease Peptic ulcer disease Mild liver disease (without portal hypertension, includes chronic hepatitis)
2	Hemiplegia Moderate or severe renal disease Diabetes with end-organ damage (retinopathy, neuropathy, nephropathy, or brittle diabetes) Tumour without metastases (exclude if more than 5 from diagnosis) Leukaemia (acute or chronic) Lymphoma
3	Moderate or severe liver disease
6	Metastatic solid tumour AIDS (not just HIV positive)

Charlson comorbidity Index is the sum of all different scores.

Generally: *0-1 points* is considered absence of comorbidity.

2 points is low comorbidity.

3 or more points is high comorbidity.

Annex VIII: THE SHORT FORM 36

SHORT FORM 36

IAS – Programa RC

Autorregistro psicométrico

Las preguntas que siguen se refieren a lo que usted piensa sobre su salud. Sus respuestas permitirán saber cómo se encuentra usted y hasta qué punto es capaz de hacer sus actividades habituales.
Conteste cada pregunta tal como se indica. Si no está seguro/a de cómo responder a una pregunta, por favor conteste lo que le parezca más cierto.

1. En general, usted diría que su salud es :

(marque un solo número)

1. Excelente	2. Muy Buena	3. Buena	4. Regular	5. Mala

2. ¿Cómo diría usted que es su salud actual, comparada con la de hace un año?

(marque un solo número)

1. Mucho mejor ahora que hace un año	2. Algo mejor ahora que hace un año	3. Más o menos igual que hace un año	4. Algo peor ahora que hace un año	5. Mucho peor ahora que hace un año

3. Las siguientes preguntas se refieren a actividades o cosas que usted podría hacer en un día normal. Su salud actual, ¿le limita para hacer esas actividades o cosas? Si es así, ¿cuánto?

(marque un solo número por cada pregunta)

ACTIVIDADES	Sí, me limita mucho	Sí, me limita un poco	No, no me limita nada
a. **Esfuerzos intensos**, tales como correr, levantar objetos pesados, o participar en deportes agotadores	1	2	3
b. **Esfuerzos moderados**, como mover una mesa, pasar la aspiradora, jugar a los bolos o caminar más de l hora	1	2	3
c. Coger o llevar la bolsa de la compra	1	2	3
d. Subir **varios** pisos por la escalera	1	2	3
e. Subir **un solo** piso por la escalera	1	2	3
f. Agacharse, arrodillarse o ponerse en cuclillas	1	2	3
g. Caminar **un kilómetro o más**	1	2	3
h. Caminar **varias manzanas** (varios centenares de metros)	1	2	3
i. Caminar **una sola manzana** (unos 100 metros)	1	2	3
j. Bañarse o vestirse por sí mismo	1	2	3

4. Durante las 4 últimas semanas, ¿ha tenido alguno de los siguientes problemas en su trabajo o en sus actividades cotidianas, a causa su salud física?

(marque un solo número por cada pregunta)

	SÍ	NO
a. ¿Tuvo que **reducir el tiempo** dedicado al trabajo o a sus actividades cotidianas?	1	2
b. ¿**Hizo menos** de lo que hubiera querido hacer?	1	2
c. ¿Tuvo que **dejar de hacer algunas tareas** en su trabajo o en sus actividades cotidianas?	1	2
d. ¿Tuvo **dificultad** para hacer su trabajo o sus actividades cotidianas (por ejemplo, le costó más de lo normal)?	1	2

1

IAS – Programa RC Autorregistro psicométrico

5. Durante las 4 últimas semanas, ¿ha tenido alguno de los siguientes problemas en su trabajo o en sus actividades cotidianas, a causa de algún problema emocional (como estar triste, deprimido, o nervioso)?

(marque un solo número por cada pregunta)

	SÍ	NO
a. ¿Tuvo que reducir el tiempo dedicado al trabajo o a sus actividades cotidianas, por algún problema emocional?	1	2
b. ¿Hizo menos de lo que hubiera querido hacer, por algún problema emocional?	1	2
c. ¿No hizo su trabajo o sus actividades cotidianas tan cuidadosamente como de costumbre, por algún problema emocional?	1	2

6. Durante las 4 últimas semanas, ¿hasta qué punto su salud física o los problemas emocionales han dificultado sus actividades sociales habituales con la familia, los amigos, los vecinos u otras personas?

(marque un solo número)

1. Nada	2. Un poco	3. Regular	4. Bastante	5. Mucho

7. ¿Tuvo dolor en alguna parte del cuerpo durante las 4 últimas semanas?

(marque un solo número)

1. No, ninguno	2. Sí, muy poco	3. Sí, un poco	4. Sí, moderado	5. Sí, mucho	6. Sí, muchísimo

8 Durante las 4 últimas semanas, ¿hasta qué punto el dolor le ha dificultado su trabajo habitual (incluido el trabajo fuera de casa y las tareas domésticas)?

(marque un solo número)

1. Nada	2. Un poco	3. Regular	4. Bastante	5. Mucho

9. Las preguntas que siguen se refieren a cómo se ha sentido y cómo le han ido las cosas durante las 4 últimas semanas. En cada pregunta responda lo que se parezca más a cómo se ha sentido usted. Durante las últimas 4 semanas ¿cuánto tiempo...

(marque un solo número por cada pregunta)

	Siempre	Casi Siempre	Muchas veces	Algunas veces	Sólo alguna vez	Nunca
a. se sintió lleno de vitalidad?	1	2	3	4	5	6
b. estuvo muy nervioso?	1	2	3	4	5	6
c. se sintió tan baja de moral que nada podía animarle?	1	2	3	4	5	6
d. se sintió calmado y tranquilo?	1	2	3	4	5	6
e. tuvo mucha energía?	1	2	3	4	5	6
f. se sintió desanimado y triste?	1	2	3	4	5	6
g. se sintió agotado?	1	2	3	4	5	6
h. se sintió feliz?	1	2	3	4	5	6
i. se sintió cansado?	1	2	3	4	5	6

10. Durante las 4 últimas semanas, ¿con qué frecuencia la salud física o los problemas emocionales le han dificultado sus actividades sociales (como visitar a los amigos o familiares)?

(marque un solo número)

1. Siempre	2. Casi siempre	3. Algunas veces	4.Sólo alguna vez	5. Nunca

2

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11. Por favor, diga si le parece CIERTA o FALSA cada una de las siguientes frases:

(marque un solo número por cada pregunta)

	Totalmente cierta	Bastante cierta	No lo sé	Bastante falsa	Totalmente falsa
a. Creo que me pongo enfermo más fácilmente que otras personas	1	2	3	4	5
b. Estoy tan sano como cualquiera	1	2	3	4	5
c. Creo que mi salud va a empeorar	1	2	3	4	5
d. Mi salud es excelente	1	2	3	4	5

3

Annex IX: THE ZUNG-SELF RATING DEPRESSION SCALE

THE ZUNG SELF-RATING DEPRESSION SCALE

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A continuación debe rodear, en una escala de 1 a 4, siendo 1 "Nunca o muy pocas veces" y 4 "La mayoría del tiempo o siempre" las afirmaciones siguientes sobre su estado de ánimo actual según si esa afirmación se encuentra muy presente en su día a día o si, por el contrario, no se identifica con esa afirmación. No hay respuestas buenas ni malas. No emplee demasiado tiempo en cada frase y conteste señalando la respuesta que mejor describa su estado de ánimo actual.	Nunca o muy pocas veces	Algunas veces	Frecuentemente	La mayoría del tiempo o siempre
1. Me siento abatido y melancólico.	1	2	3	4
2. En la mañana es cuando me siento mejor.	1	2	3	4
3. Tengo accesos de llanto o deseos de llorar.	1	2	3	4
4. Me cuesta trabajo dormirme en la noche.	1	2	3	4
5. Como igual que antes.	1	2	3	4
6. Mantengo mi deseo, interés sexual y/o disfruto de las relaciones sexuales.	1	2	3	4
7. Noto que estoy perdiendo peso.	1	2	3	4
8. Tengo molestias de estreñimiento.	1	2	3	4
9. El corazón me late más aprisa que de costumbre.	1	2	3	4
10. Me canso aunque no haga nada.	1	2	3	4
11. Tengo la mente tan clara como antes.	1	2	3	4
12. Me resulta fácil hacer las cosas que acostumbraba hacer.	1	2	3	4
13. Me siento intranquilo y no puedo mantenerme quieto.	1	2	3	4
14. Tengo esperanza en el futuro.	1	2	3	4
15. Estoy más irritable de lo usual.	1	2	3	4
16. Me resulta fácil tomar decisiones.	1	2	3	4
17. Siento que soy útil y necesario.	1	2	3	4
18. Mi vida tiene bastante interés.	1	2	3	4
19. Siento que los demás estarían mejor si yo muriera.	1	2	3	4
20. Todavía disfruto con las mismas cosas que antes disfrutaba.	1	2	3	4

1

Annex X: THE STATE-TRAIT INVENTORY

THE STATE-TRAIT ANXIETY INVENTORY (STAI)

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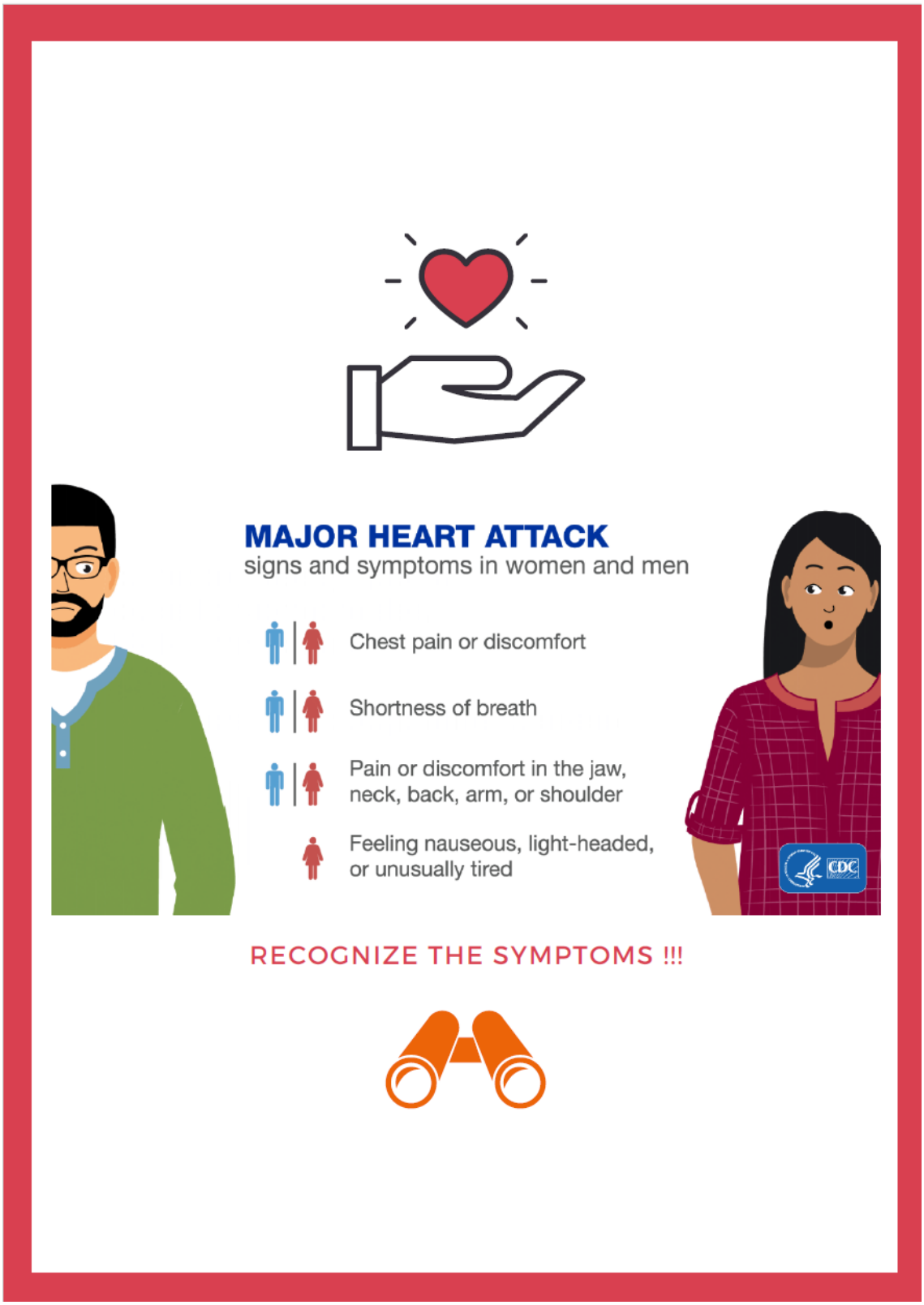
	A continuación, encontrará unas frases que se utilizar corrientemente para describirse uno a sí mismo. Lea cada frase y rodee la puntuación (0 a 3) que indique mejor como se **SIENTE USTED AHORA MISMO**, en este momento. No hay respuestas buenas ni malas. No emplee demasiado tiempo en cada frase y conteste señalando la respuesta que mejor describa su situación presente.	Nada	Algo	Bastante	Mucho
1	Me siento calmado.	0	1	2	3
2	Me siento seguro.	0	1	2	3
3	Estoy tenso.	0	1	2	3
4	Estoy contrariado.	0	1	2	3
5	Me siento cómodo (estoy a gusto).	0	1	2	3
6	Me siento alterado.	0	1	2	3
7	Estoy preocupado por posibles desgracias futuras.	0	1	2	3
8	Me siento descansado.	0	1	2	3
9	Me siento angustiado.	0	1	2	3
10	Me siento confortado.	0	1	2	3
11	Tengo confianza en mí mismo.	0	1	2	3
12	Me siento nervioso.	0	1	2	3
13	Estoy desasosegado.	0	1	2	3
14	Me siento muy "atado" (como oprimido).	0	1	2	3
15	Estoy relajado.	0	1	2	3
16	Me siento satisfecho.	0	1	2	3
17	Estoy preocupado.	0	1	2	3
18	Me siento aturdido y sobreexcitado.	0	1	2	3
19	Me siento alegre.	0	1	2	3
20	En este momento me siento bien.	0	1	2	3
	A continuación encontrara unas frases que se utilizan corrientemente para describirse uno a sí mismo. Lea cada frase y rodee la puntuación (0 a 3) que indique mejor cómo se **SIENTE USTED EN GENERAL** en la mayoría de las ocasiones. No hay respuestas buenas ni malas. No emplee demasiado tiempo en cada frase y conteste señalando lo que mejor describa como usted se siente generalmente.	Casi nunca	A veces	A menudo	Casi siempre
21	Me siento bien.	0	1	2	3
22	Me canso rápidamente.	0	1	2	3
23	Siento ganas de llorar.	0	1	2	3
24	Me gustaría ser tan feliz como otros.	0	1	2	3
25	Pierdo oportunidades por no decidirme pronto.	0	1	2	3
26	Me siento descansado.	0	1	2	3
27	Soy una persona tranquila, serena y sosegada.	0	1	2	3
28	Veo que las dificultades se amontonan y no puedo con ellas.	0	1	2	3
29	Me preocupo demasiado por cosas sin importancia.	0	1	2	3
30	Soy feliz.	0	1	2	3
31	Suelo tomar las cosas demasiado seriamente.	0	1	2	3
32	Me falta confianza en mí mismo.	0	1	2	3
33	Me siento seguro.	0	1	2	3
34	Evito enfrentarme a las crisis o dificultades.	0	1	2	3
35	Me siento triste (melancólico).	0	1	2	3
36	Estoy satisfecho.	0	1	2	3
37	Me rondan y molestan pensamientos sin importancia.	0	1	2	3
38	Me afectan tanto los desengaños, que no puedo olvidarlos.	0	1	2	3
39	Soy una persona estable.	0	1	2	3
40	Cuando pienso sobre asuntos y preocupaciones actuales, me pongo tenso y agitado.	0	1	2	3

2

Annex XI: DICLOSURE ADVERTISING MATERIAL



REHABILITACIÓ CARDÍACA

BARRERES PER A LES DONES. PERQUÈ NO HI ARRIBEN O NO LA COMPLETEN?

QUINS BENEFICIS TÉ?

Millores en...

Salut del cor
- Colesterol
- Exercici
- Deixar de fumar
- Funció cardíaca

- Menys progressió malaltia
- Menys ingressos
- Menys visites a urgències
- Dolor de pit
- Menys mediació

Salut general
- Qualitat de vida
- Força i vitalitat
- Feina i vida social
- Benestar mental
- Menys estrés, ansietat i depressió

https://aularc.es/

PARLA AMB LES TEVES FAMILIARS I AMIGUES I INFORMA-LES!!