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Research Article

Impact of Patient Empowerment on the Progression of sAcute Coronary Syndrome: Development of the Methodology for a Case-Control Study

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Abstract

Background/Aim: Cardiovascular diseases, especially Acute Coronary Syndrome (ACS), are a growing global concern. The management of ACS relies on both medical treatment and patient empowerment to reduce readmissions and emergency room visits. This study focuses on identifying factors that limit patient empowerment. The article develops the methodology to assess the impact of empowerment on ACS patients through comprehensive follow-up.

Materials and Methods: The study employs a systematic design to evaluate the impact of patient empowerment on ACS management over a 12-month follow-up period. Educational tools are integrated during hospitalization and post-discharge, with an initial assessment of patient knowledge and self-care conducted through standardized questionnaires and interviews. The nursing team, with cardiology expertise, oversees personalized interventions and collaborates with cardiologists to manage complications.

Results: Results are pending analysis. This article details the methodology for tracking patient empowerment. Future publications will present the analysis of initial evaluations and the effectiveness of educational tools. Data is expected to reveal how educational strategies during and after hospitalization impact patient empowerment and ACS clinical outcomes.

Discussion y/o Conclusions: Discussion will occur after results are available. The analysis is expected to explore how patient empowerment relates to reduced readmissions and emergency visits, and how initial assessments and educational tools address patient knowledge and self-care. Conclusions will be drawn from the results and presented in future publications. The study aims to show that integrating educational tools and proactive nursing follow-up can significantly enhance patient empowerment in ACS. Continued collaboration with cardiologists and personalized interventions will be essential for success.

Keywords: empowerment, acute coronary syndrome, nursing, health education, behavior modification, healthy habits, telephone follow-up, enhance coping, individual teaching, health practices

Introduction

Acute Coronary Syndrome (ACS) is a serious medical condition caused by the erosion or rupture of an atherosclerotic plaque, leading to the formation of an intracoronary thrombus. Its clinical manifestation ranges from unstable angina to acute myocardial infarction or sudden death, encompassing a wide range of symptoms such as acute chest discomfort, dyspnea, and left arm pain.(1-2)

On a global level, coronary diseases are the leading cause of mortality. Although a reduction in mortality has been observed in Europe over the last few decades, they continue to be the primary cause of death in Spain. Therefore, it is imperative to implement effective strategies to prevent and manage these chronic conditions.(1-2)

Patient empowerment plays a crucial role in addressing chronic diseases, enabling them to take greater control over their health and actively participate in decisions related to their care. In this context, this research focuses on evaluating the impact of an education and support program aimed at patients with Acute Coronary Syndrome (ACS) during hospitalization and post-discharge. The goal is to improve disease knowledge, promote healthy lifestyle habits, and facilitate the transition to outpatient care, aiming to empower them and enhance their long-term quality of life. (3)

One of the identified areas for improvement focuses on education and educational intervention during hospitalization and after discharge from the hospital. (4-5). These interventions, led by nursing staff, will be based on a systematic assessment of each patient's individual needs. Using tools such as specific questionnaires, we will gather information about the patient's dependency, emotional state, adherence to therapy and diet, functional capacity, level of physical activity, lifestyle habits, and health perception. This information will allow us to tailor educational interventions to each patient's specific needs.(6)

It is essential that these educational interventions continue after hospital discharge, over a period of 12 months, as this is a time when patients are most vulnerable and require close follow-up. (6- 7)

It is challenging to establish a measure of empowerment, but this has been done for several decades. In our context, empowerment in chronic patients is of interest, given that the patients we will be working with are chronic patients.

In this regard, N. Small developed a scale to measure empowerment in chronic patients for her doctoral thesis at the University of Manchester in 2012.(8) In Spain, Garcimartin, P. validated the cross-cultural adaptation of Small's scale for her doctoral thesis at the University of Barcelona, which was published in 2019 in the journal of Primary Care. (9)

In her study, Garcimartin refers to the analysis conducted by Small (among others) on empowerment, in which they consider empowerment to be both a process and an outcome resulting from communication between professionals and patients. This communication involves exchanging information about resources related to the illness, which enhances self-control, self-efficacy, coping skills, and the ability to achieve a change in one's condition.(8-9)

The work of Garcimartin is particularly relevant to this study because, although it is developed for chronic patients in general, her research primarily focuses on patients with cardiovascular disorders.(8-9)

Therefore, considering the complex nature of Acute Coronary Syndrome (ACS) treatment and recognizing the indispensable role of specialized healthcare professionals, the main objective is to develop a detailed protocol to assess the impact of an educational-training intervention on the empowerment of patients with Acute Coronary Syndrome (ACS), and its effect on associated complications, reflected in the frequency of Emergency Department visits and hospital readmissions, aiming to achieve a score on the CEPEC scale (8) (Patient Empowerment in Chronic Diseases Scale) Equal to or greater than 130. The purpose of this research study is to develop the necessary skills in patients to effectively manage their disease within the broader context of their healthcare, aiming to ensure safety, efficacy, and a significant improvement in their quality of life.(7)

Following this approach, empowerment (3)(9) forms the central core of the intervention, addressing aspects related to the patient-healthcare professional relationship, information provision, and education, aiming to foster the patient's ability to cope with and actively participate in managing their illness. This empowerment can be assessed not only directly using specific empowerment measurement tools, but also through indirect indicators such as quality of life, nutritional status, physical activity, adherence to medical treatment, patient dependency level, and emotional state. The justification for measuring these outcomes is based on the evidence provided by Clinical Practice Guidelines (2) (10) (11), which offer guidelines and recommendations based on scientific research to address the various factors involved in disease management.

The aim of this article is to describe the research protocol for evaluating patient empowerment in Acute Coronary Syndrome (ACS) following an intervention and a 12-month follow-up. It details the protocol, data collection methods, and measurement instruments.

The purpose of this study is to empower the patient to prevent complications in their condition, which can impact emergency department visits and hospital readmissions. We aim to address factors limiting patient empowerment during their hospital stay and post-discharge through a 12-month follow-up. This involves a systematic assessment of individual needs and the implementation of personalized interventions led by nursing staff. The systematic methodological approach aims to strengthen patient recovery and self-care by equipping them with knowledge about their condition and lifestyle change. (7)

The secondary objectives are to compare Emergency Department visits and outpatient consultations between groups, and to assess disease progression and quality of life factors such as adherence and psychological well-being. The study aims to enhance patient knowledge about ACS, promote healthy habits, and improve adherence to prevent complications. It also seeks to reduce anxiety, improve health perception, and tailor physical activity to patient needs while checking the consistency of analytical parameters.

Materials and Methods

Study Design

The study will use a prospective observational design with a control group, specifically a cohort study with a control group. In this design, the intervention group will receive educational information on ACS management, including aspects such as nutrition, medication, exercise, and emotional health, while the control group will only receive standard treatment without additional education or follow-up. The intervention group will benefit from digital tools, such as YouTube videos and a blog, to enhance their education. This design will allow for comparison of outcomes between the two groups to assess the impact of the educational intervention on patient empowerment. Additionally, a pre-intervention assessment will measure patients' initial empowerment levels, which will be compared to levels achieved after the intervention to evaluate its effectiveness.(12)

Study Population

Patients admitted to the cardiology hospitalization units of a tertiary hospital in the Community of Madrid with a diagnosis of Acute Coronary Syndrome (ACS) will be selected to participate in the study.

The inclusion criteria will be as follows:

• Patients hospitalized in the cardiology units of tertiary hospital (2nd north floor for the case group and 7th north floor for the control group) with a confirmed diagnosis of Acute Coronary Syndrome (ACS)).

• Aged 18 years or older and with a hospital stay of more than three days.

• Patients who willingly and consciously agree to participate in the study.

The exclusion criteria will be:

• Patients with a Barthel Index score of less than 60.

• Patients who do not have access to technological devices or refuse to use them. However, this exclusion will not apply to patients who, even if they do not have direct access to technological

Sample Size Calculation

The population served in two specific hospitalization units of the hospital, affiliated with the cardiology service, will be considered. This population will include all patients over 18 years old admitted to the cardiology service, either in the hospitalization unit located on the second floor north or in designated beds on the seventh floor north, diagnosed with Acute Coronary Syndrome (ACS).

To avoid bias in the selection of these patients, they will be numbered according to their order of admission in each of the units. Identification will be carried out based on the admission unit) and the diagnosis of the admission reason (ACS) followed by four consecutively assigned digits.

Assignment to each of the two groups will depend on the admission unit (floor). That is, patients admitted to the second floor north will be assigned to the study group, while those admitted to the seventh floor north will be assigned to the control group.

The Population Distribution by Groups

It is based on data validated by Garcimartin et al., derived from the validation of Exploratory Factor Analysis (EFA) and Confirmatory Factor Analysis (CFA) of the CEPEC scale, consisting of 47 and 30 items respectively. (8). However, specific patient application data is not available.

In a previous study(12), approved by the ethics and research committee of the tertiary hospital, corresponding to the first phase of this project, patient empowerment data was collected using the 30-item CEPEC scale. Although the study has been published, the provided data indicates that in the Cardiology group (2N), empowerment levels between 75% and 100% were observed, representing 33% of the sample, while in the Cardiology ward (7N), an 8.3% empowerment level was obtained.

Given the disparity between the two groups, a 3:1 ratio is established, suggesting they are not comparable in terms of patient empowerment.

Considering the data from the previous study (12) on patient empowerment and maintaining a 3:1 ratio between groups, the following sample size calculation is performed: Accepting an alpha risk of 0.05 and a beta risk of 0.2 in a bilateral test, 85 subjects are needed in the first group and 25 in the second group to detect a statistically significant difference between two proportions, with an expected proportion of 0.33 for group 1 and 0.08 for group 2. A follow-up loss rate of 5% has been estimated.(12)

Any patient admitted to one of the two units (2nd North, 7th North) by medical order will be included in the study if they give consent; this procedure will continue until completing the defined number of patients for each group.

A patient loss rate of 15% has been anticipated, which will be replaced using the same method in order to maintain the defined sample size for analysis.

Treatment and Patient Follow-Up

The nursing team from the participating units will be responsible for informing patients about the study and obtaining informed consent for their participation. Additionally, they will conduct patient assessments upon admission, at discharge, fifteen days post-discharge, and one month post-discharge.

The Principal Investigator (PI) will be responsible for determining if the patient continues with the intervention and for any modifications resulting from the collected data and its comparison. After hospital discharge, contact with the patient will be maintained through phone calls, during which the nurse will collect all study-related variables. If any deviation affecting the patient's clinical status occurs, the cardiology team will be informed for evaluation and adjustment of treatment, if necessary.

Variables

Main Variable

Improvement in Empowerment

Empowerment improvement will be measured using the Chronic Disease Empowerment Scale (CEPEC), a shortened scale proposed by Garcimartin, P. (8-9), the scale consists of 30 items and covers two main factors: positive attitude and symptom control, and knowledge and confidence in decision-making. Improvement in empowerment is defined as a 15-point increase on the CEPEC scale.

1	I continue to engage in interesting activities in my life despite my health problems.	1	2	3	4	5
2	I am capable of taking charge of my illness.	1	2	3	4	5
3	I am optimistic about my illness.	1	2	3	4	5
4	I have helped people with similar illnesses as mine to find different ways to cope with the situation.	1	2	3	4	5
5	My health problems prevent me from enjoying life.	1	2	3	4	5
6	I can decrease the impact of symptoms on my daily life.	1	2	3	4	5
7	I have shared my experience of taking charge of my illness with other people with health problems.	1	2	3	4	5
8	I know where to go to determine more about my illness.	1	2	3	4	5
9	I have plans to do enjoyable things despite my illness.	1	2	3	4	5
10	I have a sense of control over my illness.	1	2	3	4	5
11	Despite my health problems, I feel that I have a good quality of life.	1	2	3	4	5
12	I have information to handle difficulties related to my illness.	1	2	3	4	5
13	I have shared with others what I do to stay well.	1	2	3	4	5
14	I have the skills that help me feel in control of my illness.	1	2	3	4	5
15	I feel useful in my daily life despite my illness.	1	2	3	4	5
16	I can talk to my doctor if I change my mind about my treatment.	1	2	3	4	5
17	I can live a normal life despite my illness.	1	2	3	4	5
18	I feel confident in choosing with my doctor among different options related to my illness.	1	2	3	4	5
19	I feel actively engaged in life despite my health problems.	1	2	3	4	5
20	I have shared my knowledge about my illness with people who have similar conditions.	1	2	3	4	5
21	I participate in decisions that affect my health care.	1	2	3	4	5
22	I know how to handle difficulties related to my illness.	1	2	3	4	5
23	I try to make the most of my life despite my illness.	1	2	3	4	5
24	I understand my illness.	1	2	3	4	5
25	I have a positive outlook on my illness.	1	2	3	4	5
26	There are people with a similar illness who ask me for advice.	1	2	3	4	5
27	I have all the knowledge I need to take charge of my illness.	1	2	3	4	5
28	I know how to manage my health problems.	1	2	3	4	5
29	I have sufficient knowledge about my illness.	1	2	3	4	5
30	I feel that my life has purpose and meaning despite my health problems.	1	2	3	4	5

1 - Strongly Disagree, 2 – Disagree, 3 – Neutral, 4 – Agree, 5 - Strongly Agree

Table I: Chronic Illness Empowerment Scale (CEPEC); N. Small (Garcimartín Cerezo 2018a) (Garcimartin et al. 2019) developed a scale to measure empowerment in chronic patients; In Spain, Garcimartín, P. validated the cross-cultural adaptation of Small's scale (Garcimartín et al. 2019).

Secondary Variables

Demographic Data :

This data includes information related to the patient and their admission:

- Name
- Gender
- Age
- Patient identification number in the hospital (medical record)
- Date of admission to the hospital unit
- Date of hospital discharge
- Length of hospital stay
- Personal medical history
- Cardiovascular risk factors
- Medical diagnosis at the time of admission

The data collected in this protocol will be stored in a separate file identified with a code, which will be the same as that identifying other study data. The file containing patient-identifying data will be destroyed immediately after the study ends, once relevant data clarifications have been made.

Analytical Data :

Analytical data will be collected at admission and during follow-up to assess levels of total cholesterol, low-density lipoproteins (LDL), high-density lipoproteins (HDL), and glycated hemoglobin. These values are relevant for determining patient adherence to treatment and lifestyle changes.

Outcome Variables :

The following outcome variables were recorded:

Clinic Visits:

- Cardiology
- Other specialty visit
- Additional cardiology visit (for intervention patients)

Emergency Department Visits:

- For current cardiac condition
- Other situations

Hospital Readmission:

- For current cardiac condition
- Other situations

Barthel Index:

The Barthel Index has demonstrated inter-rater reliability, with Kappa indices ranging from 0.47 to 1.00. Likewise, intra-rater reliability has been observed with Kappa indices between 0.84 and 0.97. This index shows internal consistency, with a Cronbach's alpha coefficient ranging from 0.86 to 0.92. Empirical evidence supports the IB's ability to detect progress or decline at certain levels of functional status, although its ability to identify changes in extreme situations is limited. For example, if a person with a score of 0 experiences a state of unconsciousness and therefore increased dependence, the IB will not reflect this change. Similarly, at the upper end of the scale, both an independent person with some functional limitation and an Olympic athlete would receive a score of 100 points. These limitations are known as "floor effect" and "ceiling effect," respectively. Although these drawbacks do not represent a significant problem in clinical practice, it is important to consider them in the context of research.(13-14)

According to the specified exclusion criteria, patients with a Barthel Index score below 60 will not be included in the study.

Lawton and Brody Scale

The Lawton and Brody Scale assesses independence in instrumental activities of daily living (IADLs). Each item on the scale can be scored as 0 (unable, partially able) or 1 (able). The final score is calculated by summing the values of all responses and ranges from 0 (maximum dependence) to 8 (total independence).

The psychometric properties of the Spanish version of the Lawton & Brody IADL scale have demonstrated excellent reliability and validity. Regarding internal consistency, a Cronbach's alpha coefficient of 0.94 has been found. Exploratory factor analysis revealed factor loadings ranging from 0.67 to 0.90, while confirmatory factor analysis confirmed construct homogeneity. Concerning concurrent validity, all correlation coefficients were above 0.40.(15-17)

Adherence to the Mediterranean Diet

In the study conducted by Zaragoza Martí and colleagues in an elderly population, a modified 14-item version of the questionnaire validated in Spanish by Schröder et al. was used.(18). This modification involved removing the consumption of natural juice from item No. 4 related to fruit intake, as well as completely removing item No. 8 related to wine consumption, along with slight modifications and additions of text to facilitate completion.

On the other hand, Schöder et al..(18) examined the validity of measurement systems for adherence to the Mediterranean diet. The accuracy of dietary assessment instruments is essential for interpreting relationships between diet and disease. In this regard, the study evaluated the relative and construct validity of the 14-item Mediterranean Diet Adherence Screener (MEDAS) used in the PREDIMED (Prevención con Dieta Mediterránea) primary prevention nutritional intervention trial. The MEDAS was administered alongside a validated food frequency questionnaire to 7,146 participants in the PREDIMED study.(18)

The results showed a significant correlation between the PREDIMED score derived from the MEDAS and the PREDIMED score from the food frequency questionnaire ($r = 0.52$; intraclass correlation coefficient = 0.51), as well as with dietary intakes reported in the food frequency questionnaire. Bland Altman analysis revealed a mean estimate of the MEDAS Mediterranean diet score at 105% compared to the estimated PREDIMED score from the food frequency questionnaire. Agreement limits ranged from 57% to 153%. Additionally, multiple linear regression analyses demonstrated that a higher PREDIMED score was directly associated ($P < 0.001$) with high-density lipoprotein cholesterol (HDL-C) and inversely ($P < 0.038$) with body mass index (BMI), waist circumference, triglycerides (TG), TG:HDL-C ratio, glucose, and cholesterol:HDL-C ratio. Furthermore, there was an observed decrease in the estimated 10-year risk of coronary artery disease as the PREDIMED score increased ($P < 0.001$).(18)

In conclusion, the MEDAS proved to be a valid tool for rapidly estimating adherence to the Mediterranean diet and may be useful in clinical practice.(18)

Modified Borg Dyspnea Scale

Modified Borg Dyspnea Scale (MBDS) is used to measure the level of dyspnea during physical exertion and is associated with oxidative stress and blood lactate levels.(19-20)

International Physical Activity Questionnaire (IPAQ)

Since 1996, international experts convened by the Karolinska Institute, the University of Sydney, the World Health Organization (WHO), and the Centers for Disease Control and Prevention (CDC) have collaborated on the development, improvement, and implementation of the International Physical Activity Questionnaire (IPAQ). This instrument was first implemented in Geneva in 1998 and has subsequently been used in studies across Europe, the Americas, Asia, Africa, and Australia.(21)

The IPAQ consists of 7 questions about the frequency, duration, and intensity of physical activity (moderate and vigorous) performed in the last seven days, as well as about the time spent walking and sitting on a workday. It can be administered through face-to-face interview, telephone interview, or self-administered surveys, and is designed for adults aged 18 to 65 years. It assesses three characteristics of physical activity: intensity (light, moderate, or vigorous), frequency (days per week), and duration (time per day).(22)

Morisky Medication Adherence Scale of 8 items (MMAS-8)

The original MMAS-8 scale was evaluated by Morisky (2008) in a sample of patients with hypertension, demonstrating proven reliability and good sensitivity and predictive validity. Other studies have examined the MMAS-8 scale in patients with hypertension (De Oliveira-Filho, Morisky, Neves, Costa, & De Lyra, 2014; Hacıhasanoğlu-Aşılar, Gözüm, Capık, & Morisky, 2014; Korb-Savoldelli et al., 2012), patients undergoing warfarin treatment (Wang, Kong, & Ko, 2012), patients who have suffered myocardial infarction (Yan et al., 2014), diabetic patients (Sakthong, Chabunthom, & Charoevisuthiwongs, 2009), HIV-positive patients (Södergârd et al., 2006), and patients with Parkinson's disease (Fabbrini et al., 2013). Most of these studies have demonstrated satisfactory psychometric properties, with good convergent validity, test-retest reliability, and acceptable sensitivity and specificity.(23-26)

Beliefs about Medicines Questionnaire (BMQ)

This questionnaire investigates patient behavior regarding medication intake and barriers to therapeutic adherence. It consists of three sections: one analyzing the therapeutic regimen and comprising seven questions about how the patient took medication the previous week; a second section on beliefs, which includes two questions about treatment effects and discomfort caused; and finally, a third section on possible difficulties in remembering medication intake. One of the main advantages of this test is its applicability to evaluate adherence in patients taking multiple medications. Additionally, it allows for the identification of different types of non-adherence (e.g., distinguishing between sporadic or frequent issues), can be completed by the patient themselves, and is user-friendly. By identifying potential adherence issues, it also facilitates guidance on possible interventions. A disadvantage is that, unlike other questionnaires, it requires more time to complete.(23)

Health Questionnaire EQ-5D-5L, Spanish versión

The EQ-5D (formerly EuroQol until 1996) instrument is a measure of self-perceived health. The EQ-5D has demonstrated validity and reliability as a health measure, but its original version had some limitations, such as ceiling effects and low discriminatory ability, especially in detecting small changes in milder health states. To overcome these issues, the EuroQol Group introduced the EQ-5D-5L version in 2009, which added two levels to each dimension (no problems, slight

problems, moderate problems, severe problems, extreme problems/inability), defining a total of 3125 health states. The EQ-5D-5L has been shown to be a valid extension of the EQ-5D-3L that improves measurement properties.(27-28)

The introduction of the EQ-5D-5L, with its considerable increase in health states, has stimulated interest in finding the most suitable techniques for eliciting preferences. After conducting pilot studies in several countries, the EuroQol Group developed a valuation protocol that includes a Composite Time Trade Off (C-TTO) method and a discrete choice method, as additional information to estimate health states more accurately. The combination of both techniques in a hybrid model also addresses the problem of logical inconsistencies, meaning assigning better values to objectively worse health states, which individual techniques applied alone cannot achieve.(27-28)

Hospital Anxiety and Depression Scale, HAD

Hospital Anxiety and Depression Scale (HAD) (Zigmond & Snaith, 1983; adapted by Terol et al., 2007). This is a self-administered questionnaire comprising 14 items. It consists of two subscales, each with 7 items, rated on a Likert scale of 0-3. Odd-numbered items assess anxiety (HADA), while even-numbered items assess depression (HADD), with a scoring range of 0-21 for each subscale. Higher scores indicate greater levels of anxiety and depression. For both subscales, the authors suggest that scores above eleven indicate a "case" and scores above eight would be considered "probable case" (Zigmond & Snaith, 1983). The internal consistency for the Spanish population in a study with fibromyalgia was HADA α= 0.83 HADD α= 0.87 (Vives & Rodríguez-Muñoz, 2012).(29-30)

Scale for Measurement of Coping and Adaptation Process, Spanish Version

In the study by Gualdrón, M.A., on the cross-cultural adaptation of the scale, the results obtained include a facial validity of 95% and content validity of 0.87 with a 95% CI. The correlation coefficients for the questions ranged between r=0.84 and r=0.90, with a Cronbach's alpha of 0.87. The results are consistent and similar to previous research in other contexts.(31-32)

Goldberg's Anxiety and Depression Scale

It's a scale used to detect anxiety and depression. Each of the subscales is structured with 4 initial items to determine whether a mental disorder is likely or not, and a second group of 5 items that are only asked if positive responses are obtained from the initial questions (2 or more in the anxiety subscale, 1 or more in the depression subscale). The cutoff points are 4 or more for the anxiety scale and 2 or more for the depression scale. There's a clear improvement in sensitivity as the severity of the psychopathological disorder increases, yielding higher scores that can provide a dimensional measure of the severity of each disorder separately. (32-35)

Data Analysis

In the descriptive analysis, categorical variables will be presented with their frequency distribution and 95% confidence interval, while quantitative variables will be described using measures of central tendency and dispersion. The comparison of the primary variable will be conducted using the Chi-Square test. To assess variability in the collection of the primary variable, a preliminary assessment study of empowerment will be conducted using intra-class and inter-class correlation analysis. Additionally, agreement between measures will be analyzed using the Kappa coefficient. For quantitative variables with a normal distribution, Student's t-test or the non-parametric Mann-Whitney U test will be employed. An analysis of the relationship of each instrument with the primary variable will be performed, including correlation analysis, linear regression, and ANOVA, as appropriate for the types of related variables. To examine the influence of variables on the final outcome, a multivariate analysis will be conducted.

All analyses will be performed using the statistical package SPSS 25.0, and the significance level for tests will be set at 5% ($p < 0.05$).

Ethical Considerations

The study will comply with Law 3/2018 and Regulation (EU) 2016/679 on data protection. The Helsinki Declaration will be followed, and participants will be informed about the handling of their data. The database will be unique, with access restricted to the principal investigator, and will be deleted upon study completion. Anonymity in patient comments will be ensured in accordance with Law 41/2002.

Informed consent will be obtained from each patient, and the protocol has been approved by the hospital's ethics committee(see Annex I). Data will be coded and stored separately, with identifying information destroyed after the study. Only the principal investigator will have access to data clarifications.

Intervention Development:

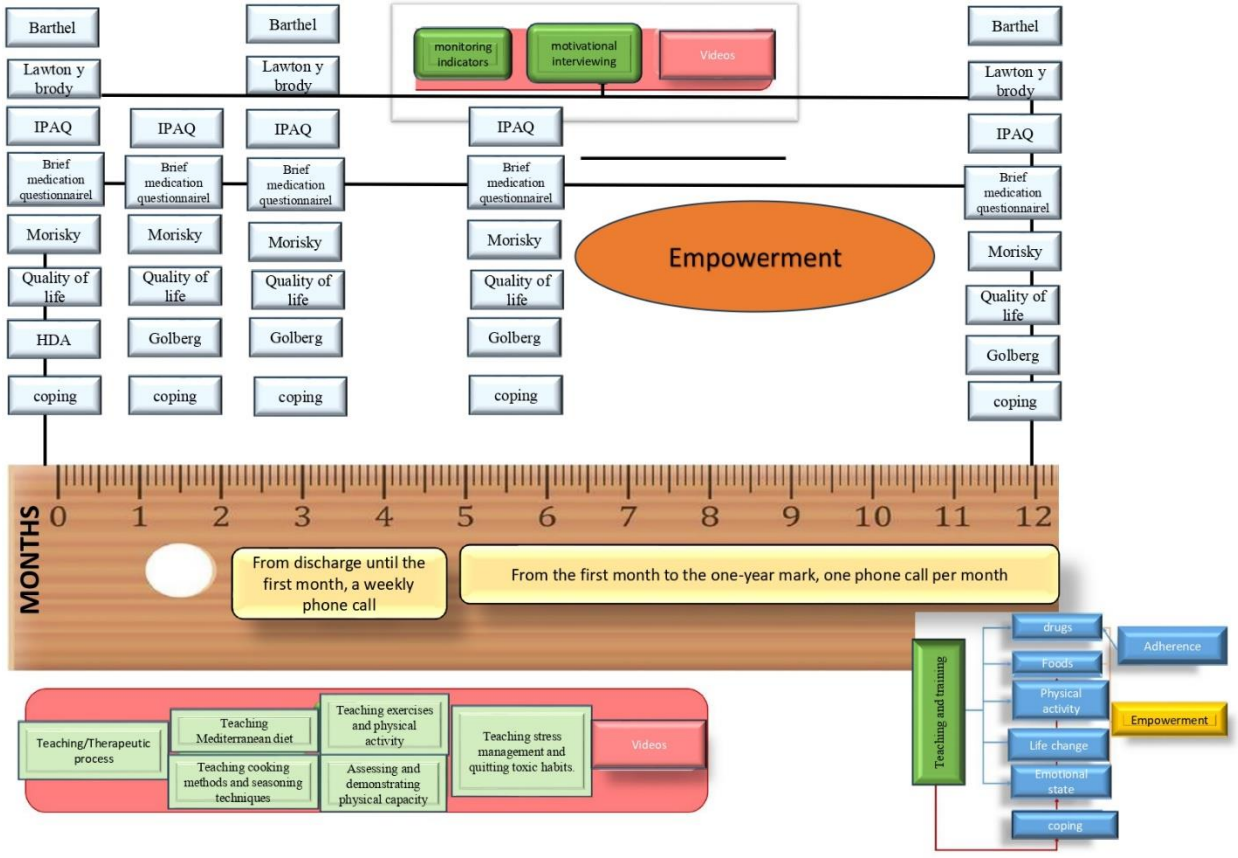

Figure 1. Intervention Development and Distribution Over Time. Self-made illustration

Figure 2: Intervention Scheme. Source: Self-made

The specific actions are related to the data obtained from different methods of information collection, focusing on the following nursing interventions (N.I.C):

• Enhance Coping

• Telephone Consultation

• Emotional Support

• Patient Contracting

• Behavior Modification

• Assist Patient to Adapt to Perceptible Stressors, Changes, or Threats

• Individual Teaching

• Health Education

• Health Practices

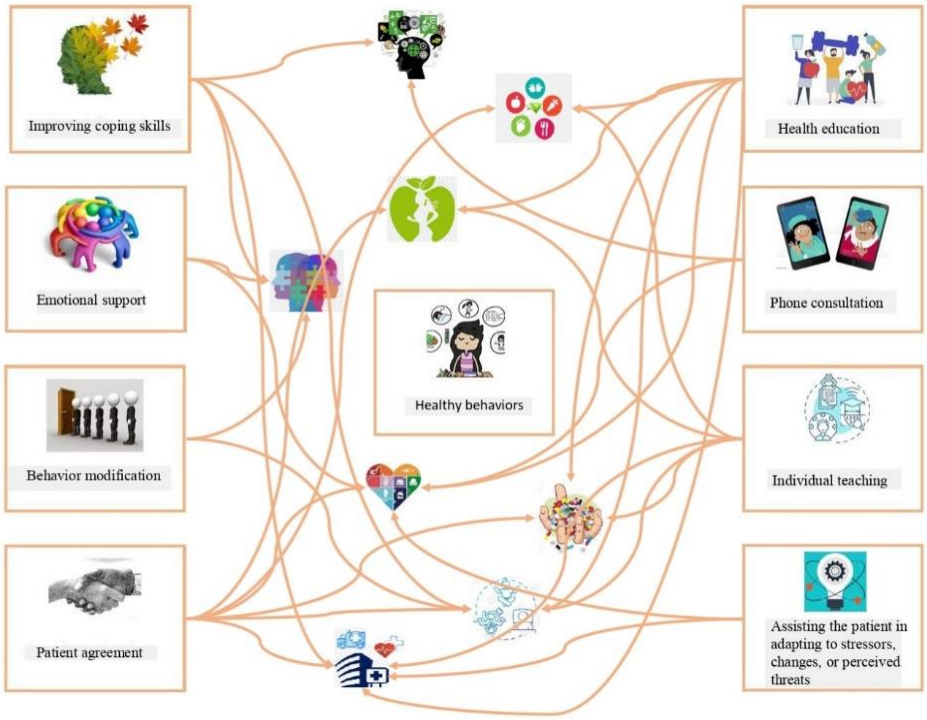

Figure 3: Interrelation of interventions with each of the elements targeted in the intervention. Source: Self-made

The relationship between different factors influencing patient empowerment is essential for designing and implementing effective interventions. Our approach focuses on each of these factors individually, recognizing their importance in improving patient health and well-being.

In this regard, the importance of using digital resources, such as YouTube videos, as complementary educational tools to strengthen the intervention and promote greater patient empowerment is emphasized. During the first month after hospital discharge and throughout the following year, we have created a series of videos that offer a valuable opportunity for patients to expand their knowledge about their medical condition and how to manage their health.

Incorporating digital resources into our intervention not only facilitates access to quality information for patients but also provides them with the flexibility to access these resources anytime and from anywhere. Furthermore, being available online, these resources can be shared and utilized by a wide range of patients, maximizing their impact and potential benefits.

In summary, the integration of digital tools into our intervention approach demonstrates our commitment to promoting patient empowerment and improving health outcomes. This combination of innovative approaches and digital educational resources will significantly contribute to the success of the intervention and the overall well-being of patients.

You can access the videos through the following link:

https://www.youtube.com/channel/UC2uFSK3IQtPTRRTu_0fF5RA

and on the following link of the blog "Cuidando de Tu Salud" (created by the principal investigator) : https://cuidandodetusaludes.wordpress.com/

The patients included in the study are those diagnosed during hospitalization for Acute Coronary Syndrome (ACS).

The study consists of three distinct phases:

• First phase: Encompasses patients diagnosed during the hospital stay.

• Second phase: Includes patients diagnosed with ACS at the time of hospital discharge, followed for one month post-discharge.

• Third phase: Involves follow-up during the first year after hospital discharge.

Regarding group assignment:

• Control group: Patients diagnosed with ACS who remain hospitalized in the cardiology unit located on the seventh floor of the north wing of HCSC.

• Case group: Patients diagnosed with ACS admitted to the cardiology hospitalization unit of HCSC, located on the second floor of the north wing, where the intervention will be applied.

The development of the intervention for patients in the case group is as follows:

A Multidimensional Perspective with Telephone Follow-up

The intervention will take place in the cardiology hospitalization unit, where patients will complete specific questionnaires at key moments of their care, coinciding with the same evaluation periods for the control group. These questionnaires will address various aspects such as quality of life, health perception, therapeutic adherence, healthy lifestyle habits (diet and exercise), and functional capacity.

Following an initial assessment, individualized educational intervention by the responsible nurse will be initiated, focusing on addressing identified deficiencies. Informational documentation on disease management will be provided, along with training on relevant digital tools.

Throughout hospitalization, all described variables will be measured while health education focused on physical activity, diet, and disease knowledge is implemented. Upon discharge, questionnaires will assess anxiety and health perception, and telephone follow-up will commence. Calls will be made weekly for the first month and monthly thereafter up to 12 months.

Telephone follow-up will facilitate close communication between the patient and the responsible nurse, enabling early detection of problems or additional support needs. In case of disease mismanagement or other concerns identified during these calls, an in-person appointment with the responsible nurse will be scheduled, coordinating with cardiologists if necessary.

Participation in cardiac rehabilitation will be encouraged, assisting with appointment management as needed. At 6 and 12 months post-discharge, additional data will be collected via questionnaires and scales, along with a one-month follow-up phone call.

This comprehensive approach, combined with regular telephone follow-up, aims to improve both clinical outcomes and the quality of life for ACS patients, promoting their empowerment and autonomy in managing their long-term health. Telephone follow-up provides an opportunity for ongoing support, monitoring patient progress, and addressing any emerging concerns.

Development of the intervention in the control group (description of standard practice developed in the hospital):

During hospitalization, patients diagnosed with Acute Coronary Syndrome (ACS) receive standard care from the cardiovascular education nurse. This care includes providing a detailed informational brochure about the disease and related recommendations. This practice is common in both the control and case groups ; however, in the control group, specific evaluations by the responsible nurse and subsequent one-year telephone follow-up are not conducted.

Additionally, no digital tools are employed as part of the intervention to foster patient empowerment.

Upon admission, the study's responsible nurse will request participating patients in this group to complete the patient empowerment questionnaire, along with other relevant questionnaires. Furthermore, hospital readmissions and emergency room visits by patients will be recorded through the hospital control system. These data will be used to make comparisons between the groups.

Comparison between study groups will occur at specific time points: upon admission, at 15 days post-hospital discharge, at one month, three months, six months, and one year. At each of these times, the same questionnaires will be administered, and the same general data will be collected from both groups. This will allow for a systematic and comparative evaluation of patient progression over time and to determine any significant differences between the groups in terms of variables of interest, such as quality of life, therapeutic adherence, health perception, and other relevant aspects for the study.

Results:

The results are currently pending analysis. The article focuses on the detailed description of the methodology used for monitoring patient empowerment. The results of the initial assessments and the effectiveness of the integrated educational tools will be analyzed and presented in future publications. It is anticipated that the data will reveal how the implementation of educational strategies during and after hospitalization influences patient empowerment and clinical outcomes related to Acute Coronary Syndrome (ACS).

Discussion:

The discussion will be addressed once the results are available. The analysis is expected to explore the relationship between patient empowerment and the reduction in readmissions and emergency room visits. It will discuss how the lack of an adequate initial assessment impacts patient knowledge and self-care, and how educational tools can mitigate these issues. The effectiveness of the follow-up protocol and personalized interventions will be evaluated in terms of their impact on patient recovery and self-care.

Possible limitations of the study following the development of the methodology include the lack of randomization in the selection of cases and controls, which may introduce selection bias and affect the external validity of the results, as well as complicate group comparisons. Without random assignment, controlling for confounding factors is challenging, potentially leading to incorrect conclusions about the relationship between empowerment and clinical outcomes. A 12-month follow-up may not capture all long-term effects, and findings may not be generalizable to a broader population due to specific participant characteristics. Additionally, the influence of external interventions and information bias due to non-uniform assessment methods could affect the results. Finally, the absence of randomization may present challenges in bias correction and causality interpretation, impacting the robustness of the conclusions. These limitations should be considered when interpreting the results and designing future research.

Conclusions:

Conclusions will be formulated after analyzing the results and will be included in future publications. The study is expected to demonstrate that integrating educational tools and proactive follow-up by the nursing team can significantly enhance patient empowerment with ACS. Ongoing collaboration with cardiologists and the personalization of interventions will be key to the success of the protocol. The article will highlight the importance of a systematic methodological approach to strengthen patient recovery and their ability to manage their condition effectively.

This detailed methodological approach will provide a solid foundation for future evaluation of the results and will enable the development of more effective intervention strategies in managing ACS.

Conflict of Interest statement

There are no conflicts of interest among the authors of the work

Funding Statement

The study has not received any funding

Data Acquisition

The data has been obtained following the data protection and patient privacy law and endorsed by the Ethics Committee for Research at the Hospital Clínico San Carlos, with the approval of the study protocol.

Statistics:

Of the authors, two have specialized training in statistics. Specifically, Professor Pacheco del Cerro, Enrique, has conducted the analysis.

Author Responsibility:

Affirm that methods used in data analyses are appropriately applied within the study design.

Agree to take responsibility for the statistical approach's appropriateness, conduct, and interpretation.

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