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Effectiveness and cost-effectiveness of a virtual intervention (VCoP) to improve the empowerment of patients with ischaemic heart disease: study protocol of a randomized controlled trial.

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TITLE

Effectiveness and cost-effectiveness of a virtual intervention (VCoP) to improve the empowerment of patients with ischaemic heart disease: study protocol of a randomized controlled trial.

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ABSTRACT

Introduction

Virtual Communities of Practice (VCoP) offer ubiquitous access to information and exchange possibilities for people in similar situations, which might be especially valuable for the self-management of patients with chronic diseases. In view of the scarce evidence on the clinical and economic impact of these interventions on chronic conditions, we aim to evaluate the effectiveness and cost-effectiveness of a VCoP in the improvement of the activation and other patient empowerment measures in patients with ischemic heart disease (IHD).

Methods and analysis

A pragmatic randomised controlled trial will be performed in Catalonia, Madrid and Canary Islands, Spain. Two hundred forty-six patients with a recent diagnosis of IHD attending the participating centres will be selected and randomized to intervention or control group. The intervention group will be offered participation for 12 months in a VCoP based on a gamified web 2.0 platform where there is interaction with other patients and a multidisciplinary professional team. The control group will receive usual care. The primary outcome will be measured with the Patient Activation Measure questionnaire at baseline, 6, 12 and 18 months. Secondary variables will include: sociodemographic and clinical variables; knowledge test (Questionário de Fatores de Risco Cardiovascular), attitudes (Self-efficacy Managing Chronic Disease Scale), adherence to Mediterranean diet (Mediterranean Diet Questionnaire), level of physical activity (International Physical Activity Questionnaire), depression (Patient Health Questionnaire), anxiety (Hospital Anxiety Scale), medication adherence (Adherence to Refill and Medication Scale), quality of life (EQ-5D-5L) and health resources use. Data will be collected from self-reported questionnaires and electronic medical records.

Ethics and dissemination

The trial was approved by Clinical Research Ethics Committee of Gregorio Marañón University Hospital in Madrid, Nuestra Señora de Candelaria University Hospital in Santa Cruz de Tenerife and

IDIAP Jordi Gol in Barcelona. The results will be disseminated through workshops, policy briefs, peer-reviewed publications, local/international conferences.

Registration

ClinicalTrials.gov Identifier: NCT03959631

Strengths and limitations of this study

- We will experimentally test an innovative learning intervention based on a VCoP for patient empowerment, for which the literature lacks experimental evaluations.
- VCoP can enhance communication between CoP members in different geographic locations and even from different time zones.
- Participation rate can be low as similar experiences have shown; we will include the active role of a community manager, weekly emails as reminders and a gamified competitive score system to boost participation.
- Participation in the intervention group will require a minimum level of digital literacy so, the results could not be generalized to all patients.
- Patients belonging to the control group and intervention group could receive different type of self-management support depending on the centres where the care is provided.

INTRODUCTION

In Western countries, ischemic heart disease (IHD) is a major public concern as, and although mortality from IHD has been significantly reduced since 2000, it remains as a leading cause of death (50.6 deaths / 100,000 inhabitants in Spain and 106.6 deaths / 100,000 inhabitants in the United States in 2016) (1). In Spain 32,325 people died from IHD in 2017, according to the National Institute of Statistics (2). Patients with IHD may have a stable disease or an acute coronary syndrome, which could present with or without ST segment elevation. In addition, some patients may have left ventricular dysfunction and heart failure (3–5).

For the treatment of IHD, in addition to the pharmacological treatment and, if necessary, interventional procedures, it is essential to manage cardiovascular risk factors such as smoking cessation, blood pressure, lipids and diabetes control, adherence to a Mediterranean diet, active lifestyle and prevent obesity. Moreover, for the secondary prevention of IHD, cardiac rehabilitation programs are beneficial for patients, improving exercise capacity, quality of life and psychological well-being (6–8). The active role of the patient is crucial along with the support of health care providers to achieve a successful secondary prevention of IHD.

The empowerment and self-management of patients with chronic conditions is becoming one of the main objectives in health care, especially in primary care (PC). The European EMPATHiE project (9) defines the empowered patient as one who "has control over the management of the conditions of their daily life, actively tries to improve his/her quality of life and has the necessary knowledge, skills, attitudes and self-perception to adjust his/her behaviour and work in partnership with others when necessary, to achieve optimal well-being".

One of the domains included in patient empowerment is the level of patient activation. Patient activation incorporates a combination of knowledge about the illness, ability and self-confidence in the management of the medical conditions (10). It is associated with healthy behaviours, good chronic disease metrics, and reduced morbidity and unplanned hospitalizations (11–15).

Interventions aimed at empowerment are intended to provide patients (and their informal caregivers, when appropriate) with the ability to participate in decisions related to their illness to the extent they wish, develop self-confidence, self-esteem and skills to face the physical, emotional and social impact of the disease in their daily lives (16,17).

Virtual Communities of Practice (VCoP) offer ubiquitous access to information and exchange possibilities for people in similar situations, which is especially valuable in patients with chronic diseases. A CoP is a group of individuals who participate in a common activity and experience and create a shared identity and deepen their knowledge and experience in the area through a continuous interaction that strengthens their relationships (18). In this context, a group of patients with the same illness such as IHD, could benefit from an intervention of these characteristics where they can share resources and information in addition to having the possibility of receiving peer and professional support.

There is little research on the effect of VCoP in terms of their clinical and economic impact and on the empowerment of patients with chronic diseases, especially with IHD (19,20). We propose to address this gap and, thus, present the protocol of a randomized controlled trial, which mainly aims to evaluate the effectiveness and cost-effectiveness of a VCoP to improve the activation and other measures related with patient empowerment in patients with IHD.

METHODS AND ANALYSIS

Study design

We plan a pragmatic randomized controlled multicentre trial (*e*-mpodera[2]), with two parallel arms and 18-month follow-up.

Study setting

Virtual setting for intervention arm. Usual care will be provided at primary care practices (PCPs) and outpatient specialized clinics in Catalonia, Madrid and Canary Islands in Spain.

Eligibility criteria

Patients with a recent diagnosis of IHD will be screened for the following eligibility criteria:

Inclusion criteria

Age ≥ 18 years; active diagnosis in the electronic medical record (EMR) of IHD (ICPC-2 codes K74-76; or ICD-9 codes 410, 411, 411.8, 413, 414 y 414.9) in the year prior to inclusion in the study; Internet at home or Smartphone; be able to follow the requirements of the study (e.g. digital literacy); have signed the informed consent (Additional file 1).

[About here link to Additional file 1 on Informed consent].

Exclusion criteria

Institutionalized, terminal illness, physical or mental disability that limit the ability to answer the questionnaires or when telephone / email contact is not available in the PCPs/hospitals' databases.

Interventions

VCoP group

"*e*-mpodera[2]" is a gamified VCoP on a web 2.0 platform based on the exchange of experiences and knowledge through participatory learning (21). It will provide educational, playful elements and tools that will facilitate the learning and transfer of knowledge and attitudes among patients with IHD and with health care professionals. The structure and components will be designed according to the needs and specifications of patients with IHD recruited in an earlier stage using a co-creation methodology with face-to-face sessions and virtual activities (forums and interactions) that incorporated a personalized itinerary – Patient Journey Map - (published elsewhere) and with the use of various types of content including readings, resources, videos, games and virtual sessions (21).

Patients will have access to multidisciplinary professional support as needed and according to what was identified in the content-design stage (published elsewhere) will potentially include general practitioners, cardiologists, psychologists, self-care and self-management specialists, nutritionist and others as necessary. Various thematic areas related to the empowerment of

patients and self-care of IHD will be progressively covered: health competence, self-efficacy and activation improvement, behavioural changes, lifestyle / signs / symptoms monitoring, technical skills, chronic disease acceptance and shared decision-making. Special emphasis will be given to the changes recommended by European Guidelines (22) for self-management of IHD including monitoring changes in symptoms, stress management, mental health and adherence to medication, diet, exercise plans, sodium cholesterol, and alcohol restriction and tobacco abstinence. The active role of a community manager, weekly emails as reminders and a gamified competitive score system will boost participation**.**

Usual care group

Patients allocated to the control group will continue with their usual self- and professional care according to the local guidelines (3–5).

Outcomes measures

Primary outcome

The primary outcome will be the patient activation level using the Patient Activation Measure (PAM) questionnaire that assesses activation in patients with chronic diseases (12). The questionnaire consists of 13 items that assesses knowledge, skills and confidence of people for self-care, measured by a Likert 1-4 scale with a total score between 0 and 100 (100 identifies the patients with the highest level of activation). The Spanish translated version has been validated in patients with chronic diseases and has demonstrated a similar behaviour to the original instrument with good validity and reliability properties (23). It has been used in previous studies by this research team (24).

Secondary outcomes

For the effectiveness of the VCoP, we will record the following secondary measures:

- Clinical variables such as body mass index, lipid profile (HDL-C, LDL-C), smoking status, number and frequency of angina episodes will be collected through researcher's developed online

questionnaire that will be fulfilled by health care professionals combined with information from the EMR.

- Knowledge about the disease will be assessed through a self-administered online questionnaire based on the Questionário de Fatores de Risco Cardiovascular (Q-FARC) (25–27), previously translated from the English version and adapted to the Spanish population.
- Patients' attitudes to self-care will be evaluated using the self-administered Self-efficacy Managing Chronic Disease Scale (SMCDS) (28), translated into Spanish (29) and used in patients with heart failure (30).
- Adherence to Mediterranean diet will be assessed with the Mediterranean Diet questionnaire (31), validated in the Spanish population in the PREDIMED study (32–34).
- Physical activity will be measured using the International Physical Activity Questionnaire (IPAQ), translated and adapted to the Spanish language (35). Patients will be classified into three categories (low, medium and high) according to the index of physical activity (product of the intensity - in METS - by the frequency,) and the duration of the activity.
- Depressive disorders will be detected by the Patient Health Questionnaire-9 (PHQ-9) (36), validated in Spanish with similar behaviour to the original and good acceptance (37).
- Anxiety will be assessed using the Hospital Anxiety and Depression Scale (HADS-A scale) (38), a 14-item questionnaire validated in PC in Spain (39,40), with special interest and usefulness in the context of PC. It is a measure composed of two sub-scales (HAD-A: anxiety and HAD-D: depression), of 7 items each that are scored from 0 to 3. The authors recommend a threshold of 8 points to detect possible cases of anxiety. One of the main virtues of this tool is the suppression of somatic symptoms. However, in patients with IHD it underestimates people with depression (41), while the sub-scale HADS-A has good specificity and predictive value for measuring anxiety in this PC (42).
- Adherence to medication will be assessed with the Adherence Refill and Medication Scale (ARMS-e) (43), validated in Spain and used to measure adherence to medication in patients

with chronic diseases. It consists of 12 questions and there is no cut-off point, the lower the score, the better the adherence. To quantify adherence, a value of 1 to 4 (never, sometimes, almost always or always) is assigned to each of the responses according to a Likert-type scale.

- Quality of life related to health (HRQoL) will be described and assessed with the EQ-5D-5L index (44), a generic and standardized instrument developed by the EuroQoL Group, and prepared in several languages, including Spanish, and used in PC (45). It relates the HRQoL with the amount of life and offers a score for the gains in health, the Quality Adjusted Life Year (QALY). The descriptive EQ-5D system comprises 5 dimensions (mobility, personal care, daily activities, pain / discomfort and anxiety / depression).

Explanatory and adjustment variables

- Sociodemographic: age, sex, nationality, Autonomous Community of residence (Catalonia, Madrid or Canary Islands), marital status (married/partner, single, separated/divorced, widowed), living alone (yes/no), educational level (incomplete primary education, complete primary education, secondary education, university or equivalent studies), income level and employment status (46).
- Morbidity related: type of IHD (stable angina, unstable angina, MI), duration of IHD (months), current diagnosis of heart failure in EMR (K86), left ventricular ejection fraction ($\leq$ 30%, 30-35%, 35-45%, >45%), NYHA class (I-IV), number and description of chronic concomitant diseases (47), pharmacological treatment (acetylsalicylic acid or clopidogrel/ticagrelor/prasugrel, beta-blockers, statins, angiotensin-converting enzyme (ACE) inhibitors, angiotensin II receptor blockers, other treatments), cardiac catheterization (yes/no) and participation in a cardiac rehabilitation program before and during the study period (yes/no).
- Use of health care resources: primary care (PC) visits, visits to the emergency department, visits to specialists, number of hospitalizations, lengths of stay, prescribed medications, use of diagnostic tests.

- Loss of productivity: self-administered questionnaire about work absences related to the illness.
- Use of the VCoP.

This information will be collected from a patient self-reported questionnaire that the research team will elaborate combined with information from the EMR. VCoP use data will be collected through the platform database.

Adverse events

All significant adverse events as well as unintended consequences for each group will be collected and described by the site researcher, nominated for each PCP and hospital, and reported to the core team. A special form to report trial-related adverse events has been developed and distributed.

Participant timeline

Primary and secondary outcome measures will be collected before the start of the VCoP intervention and at 6, 12 and 18 months. See Table 1.

[About here: Table 1 on Schedule of enrolment, interventions, and assessments (SPIRIT checklist)].

Sample size

The necessary number of patients to detect, by means of independent means test, an average minimal important difference of 4 points (SD 10) in the PAM questionnaire (12,23) between the intervention and usual care group, is 123 patients per arm. For this calculation we assume an alpha error of 0.05, power of 80% and size is increased by the estimation of a 20% loss.

Recruitment

Patient recruitment will be organized on each Autonomous Community (Catalonia, Madrid or Canary Islands). The recruitment will be supported by informative meetings with directors and health care professionals (general practitioners, nurses, cardiologists) from the participating centres. In these meetings, a 10-minute presentation describing the study aim, planned time frame and tasks to be carried out by health care professionals, expected resources utilization and

funding procedures will be detailed. Patients that fulfil inclusion criteria will be actively encouraged by their health care professionals to participate by providing information about the trial and collecting their informed consent and contact details (e.g. phone number / email). The research team will invite potential participants via phone and mail to access the "*e*-mpodera²" platform where they will be provided with a unique registration code (Figure 1). Patients will be consecutively included in the study; recruitment will be continuous until the sample size is reached.

[About here: Figure 1 on Flow of participants].

Allocation and blinding

Two hundred and forty-six patients will be randomly assigned to the intervention (VCoP) or control group. The randomization will be central and automatically performed by the online "*e*-mpodera²" platform and the assigned group will be communicated to the patient once he or she has entered the platform and completed baseline assessment (Figure 1). Lack of knowledge of the randomization sequence by the professionals who participate in the recruitment of patients will therefore be ensured. The intervention group will be taken directly to the registration page of "*e*-mpodera²" VCoP, where they will receive a personalized message to welcome them into the platform. To warrant patient participation and cooperation, this type of intervention cannot be blinded to patients. Data analysists will be blinded to the assignment of the intervention.

Data management

In order to maintain participant confidentiality all information will be stored with anonymized ID code numbers. The ID code numbers will be unrelated to participants' identifiers, except in a central file with the participants' contact details. All data will be stored on an electronic database management system located on a secure server with password-controlled access provided for research data collection. Databases will be designed to avoid downloading inappropriate values for every variable. Trial monitoring will be the responsibility of the core research team in charge of

all quality control activities, assessing adherence to the trial protocol: timely work plan execution and comprehensiveness of data acquisition and data quality.

The Research Ethics Committees, the representatives of the Health Authority in matters of inspection and the personnel authorized by the Promoter, may only access to check personal data, clinical study procedures and compliance with the rules of good clinical practice (always maintaining the confidentiality of information).

Statistical analysis

Sociodemographic and clinical baseline variables for both groups will be analysed by descriptive methods (mean (SD), median (range), n (%)). The VCoP effect on the primary and secondary outcomes will be examined by means of multilevel linear regression, with patients as a fixed factor (level 1) and general practitioners as a random factor (level 2), adjusting for baseline scores of the dependent variable. We will perform the analyses on an intention-to-treat basis (a sensitivity analysis on the per-protocol population will be also performed). Multiple imputation will be used for missing data, if applicable (Markov Chain Monte Carlo multivariate imputation algorithm, with 10 imputations per variable). Analyses will be carried out with the statistical software R Core Team (2014) http://www.R-project.org/ and PASW Statistics 18.

Cost-effectiveness analysis of the VCoP (5 months).

We will carry out an economic evaluation in which the costs and the results of the VCoP will be compared to the usual care following the recommendations of the guidelines for the management of patients with IHD (3–5), during the period of the clinical trial. The accepted analytical methods by the scientific community will be followed (48). The main outcome measure will be the incremental cost per gained QALY. The utilities for the estimation of the QALYs will be obtained through the EQ-5D-5L questionnaire (44) that will be completed by the patient at the beginning of the study and at each follow-up visit.

The perspective of the economic analysis will be that of the National Health System, including only direct health costs, and of the social perspective, including indirect costs associated with the loss

of productivity of patients. In addition to including the short-term costs (development and implementation of the VCoP), the costs observed during the follow-up will be included. The unit costs will be obtained from the eHealth cost database (*Oblikue Consulting*) and from public sources such as rates and PVP. The utilization of resources will be obtained from a patient self-reported questionnaire described in the outcome section. In addition, information about work absences related to the illness will be requested. As a summary result measure, the incremental cost-effectiveness ratio (ICER) that results from dividing the difference in costs between choices by the difference in effectiveness will be used. Non-parametric methods based on bootstrap simulations will be used to calculate confidence intervals in the ICER. The same nonparametric methods will be used to calculate the acceptability curve that represents the probability that each choice will be cost-effective for different cost-effectiveness thresholds. Finally, deterministic sensitivity analyses (one, two or several ways) will be carried out in order to assess the impact of the parameters on the cost-effectiveness results of the VCoP.

Patient and public involvement

This protocol was developed without patient or public involvement. A group of patients with IHD will actively participate in a content-design previous stage using a co-creation methodology with face-to-face sessions and virtual activities.

ETHICS AND DISSEMINATION

The study is registered on ClinicalTrials.gov. code NCT03959631 (https://clinicaltrials.gov/ct2/show/NCT03959631?recrs=b&type=Intr&cond=coronary+heart+disease&age=1&draw=2). Informed consent will be obtained from each participant before randomization. The project received ethics approval from the local Committees at each participating Autonomous Community: Clinical Research Ethics Committee of Gregorio Marañón University Hospital in Madrid, Nuestra Señora de Candelaria University Hospital in Santa Cruz de Tenerife and from the coordinating centre IDIAP Jordi Gol in Barcelona (19/053-P). Patients will be

personally informed by their physicians or nurses about the study and the possibility to participate during a programmed consultation. They will receive written information of the proposed research project, including information regarding the aims of the project, the duration of the participants' involvement, the expected benefits to the participant and the procedures involved in the participation. Recruiters will emphasize that enrolment in the study is voluntary and that participants can withdraw at any moment of the project and that any decision they take in this respect will have no bearing on the medical care received. Once patients have signed the written informed consent, a researcher from the "*e*-mpodera²" team will contact them via phone and/ or mail to provide further information along with the necessary data (username and password) to login into the online platform. Additionally, recruiters will highlight that information generated by the study will be published, but no identification details will be divulged. Patients and health care providers will be informed of whom to contact in case of any query and research staff will be available to answer questions.

We will prepare presentations to disseminate the study findings to healthcare stakeholders and patients, and at relevant national and international conferences. We aim to publish the results of the trial in peer-reviewed journals.

TRIAL STATUS

The recruitment of patients in each region will start in March 2020. The estimated end date of the recruitment for this study is August 2020.

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CONTRIBUTORS

AIG wrote the initial draft of the protocol. CO is the guarantor of the trial. AIG, CO, LP, DK, VP and MB conceived the project. SG and AR provided the methodological guidance. AT, VR, ATC, JMR, JCR, SD, LM, JGG, NVC, AR, JCdC, MM, YdR, ET and ABR are co-supervisors of this project, providing advice at all stages of the development of the protocol, and contributed to the revision of the manuscript. All authors read and approved the final manuscript.

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DISCLAIMER

The funder had no role in developing the protocol or obtaining the results for this review.

COMPETING INTERES

None declared

DATA SHARING

No additional data available

PATIENT AND PUBLIC INVOLVEMENT

Not required

WORD COUNT

613 3,225

Table 1. Schedule of enrolment, interventions, and assessments (SPIRIT checklist) (49)

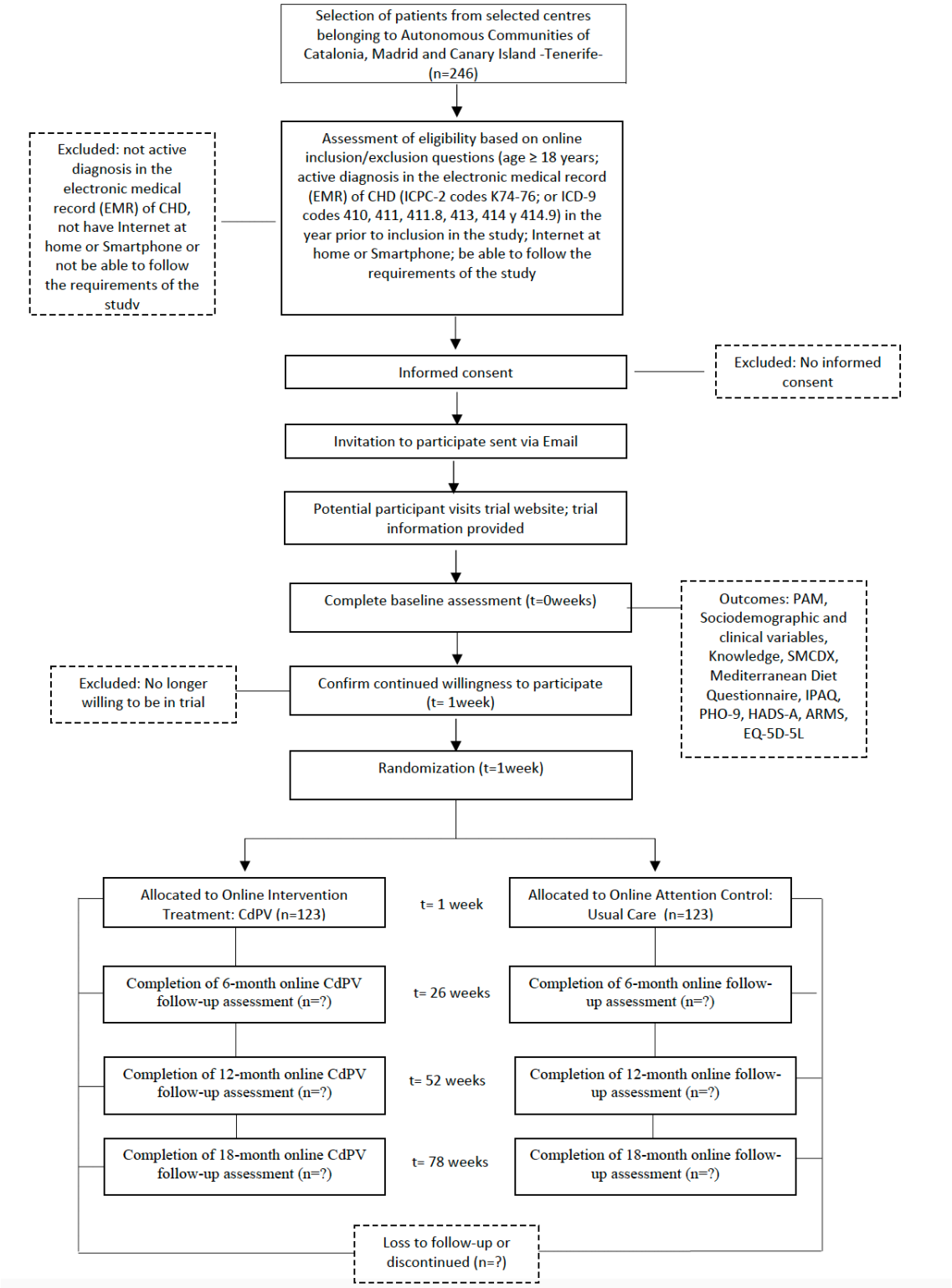
	STUDY PERIOD					
	Enrolment	**Allocation**	**Post-allocation**			**Close-out**
TIMEPOINT	***Before randomization***	**0**	***Baseline***	***6 months***	***12 months***	***18 months***
ENROLMENT:						
Eligibility screen	X					
Informed consent	X					
Allocation		X				
INTERVENTIONS:						
VCoP						
Usual care						
ASSESSMENTS:						
PAM	X			X	X	X
Sociodemographic and clinical variables	X			X*	X*	X*
Knowledge	X			X	X	X
SMCDX	X			X	X	X
Mediterranean Diet Questionnaire	X			X	X	X
IPAQ	X			X	X	X
PHQ-9	X			X	X	X
HADS-A	X			X	X	X
ARMS-e	X			X	X	X
EQ-5D-5L	X			X	X	X
Use of resources						
Use of VCoP						

Adverse events						

HADS-A = Hospital Anxiety and Depression Scale; IPAQ = International Physical Activity Questionnaire; ARMS-e = Adherence Refill and Medication Scale; PAM = Patient Activation Measure; PHQ-9 = Patient Health Questionnaire; SMCDS = Self-efficacy Managing Chronic Disease Scale; VCoP = Virtual Community of Practice.
*Follow-up of just clinical variables

Figure 1. Flow of participants (54)

Figure 1. Flow of participants (49)



Additional file 1. Informed consent

HOJA DE INFORMACIÓN AL PACIENTE

FASE ENSAYO CLÍNICO

INTRODUCCIÓN

Estimado/a Sr/a:

Le comunicamos que se está desarrollando la puesta en marcha del ensayo clínico denominado **"Efectividad y coste-efectividad de una intervención virtual (Comunidad de Práctica) para la mejora del empoderamiento de pacientes con cardiopatía isquémica en atención primaria: ensayo controlado aleatorizado por conglomerados" (Cataluña: PI18/01404/, Madrid: PI18/01397, Canarias: PI18/01333).**

Este estudio ha sido aprobado por los Comités Éticos de los centros participantes de acuerdo con la legislación vigente, la Ley Orgánica 3/2018, de 5 de diciembre de Protección de Datos Personales y garantía de los derechos digitales, y a la aplicación del Reglamento (UE) 2016/679 del Parlamento europeo y del Consejo de 27 de abril de 2016 de Protección de Datos (RGPD) por el que se regula este tipo de estudios.

Nuestra intención es tan solo que usted reciba la información correcta y suficiente para que pueda evaluar y juzgar si quiere o no participar en este estudio. Para ello lea esta hoja informativa con atención y nosotros le aclararemos las dudas que le puedan surgir después de la explicación. Además, puede consultar con las personas que considere oportuno.

PARTICIPACIÓN VOLUNTARIA

Debe saber que su participación en este estudio es voluntaria y que puede decidir no participar o cambiar su decisión y retirar el consentimiento en cualquier momento, sin que por ello se altere la relación con su médico ni se produzca perjuicio alguno en su tratamiento.

¿Quiénes son los investigadores?

El equipo de investigación está formado por un equipo multidisciplinar (medicina, psicología, estadística y evaluación de servicios sanitarios, médicos de familia, enfermeras, cardiólogos) cuyos miembros pertenecen a las siguientes instituciones:

Fundación Avedis Donabedian, Gerencia Asistencial de Atención Primaria (GAAP) del Servicio Madrileño de Salud y Servicio de Evaluación del Servicio Canario de la Salud (SESCS).

Este proyecto ha surgido de una iniciativa colaborativa en el marco de la Red de Investigación en Servicios de Salud en Enfermedades Crónicas (REDISSEC).

DESCRIPCIÓN GENERAL DEL ESTUDIO

¿Por qué se hace este estudio?

Para evaluar la efectividad de una de una Comunidad de Práctica (CdP) virtual dirigida a pacientes con cardiopatía isquémica (CI) para mejorar su conocimiento, habilidades y autoconfianza para gestionar su propia salud y de la asistencia sanitaria que recibe.

¿Quién puede participar?

Si usted es mayor de 18 años, tiene cardiopatía isquémica, dispone de internet en su hogar y/o Smartphone.

Procedimiento del estudio:

Existirán dos grupos de estudio, Grupo de intervención (GI) y Grupo Control (GC), y a los pacientes se les asignará uno u otro al azar. En el caso de que usted quisiera participar en el estudio podría estar en cualquiera de los 2 grupos.

Si usted desea participar, ¿en qué consiste su participación?

La duración del estudio será de 18 meses. Al comienzo del estudio, a los 6, 12 y 18 meses, los participantes cumplimentarán unos cuestionarios online sobre aspectos relacionados con el nivel de activación de cada participante en las decisiones relacionadas con su salud (cuestionario PAM), el conocimiento de la enfermedad, la actitud hacia la enfermedad, la adherencia a la dieta mediterránea, la actividad física y algunos cuestionarios relacionados con variables psicológicas. Cumplimentar estos cuestionarios le llevará aproximadamente 30 minutos.

Si de forma aleatoria cae en el Grupo de intervención, se le ofrecerá participar durante 18 meses en una Comunidad de Práctica Virtual (CdPv) basada en una plataforma web 2.0. Se pondrá a disposición un enlace (vía email) para registrarse e iniciar la participación voluntaria.

Dentro de esta CdPv usted podrá disponer de elementos educativos, lúdicos y herramientas para facilitar el aprendizaje y la transferencia de conocimientos y de sus actitudes. Además, se trabajarán diversas temáticas relacionadas con: competencias en salud, técnicas de

autoeficacia, estilos de vida, aceptación de la enfermedad crónica y toma de decisiones compartida, dieta, planes de ejercicio, gestión del estrés, etc.

Si de forma aleatoria cae en el Grupo Control, usted seguirá los cuidados y atención propias de la práctica clínica habitual.

RIESGOS Y BENEFICIOS DE LA PARTICIPACIÓN EN ESTE ESTUDIO

No se prevé ningún tipo de riesgo físico ni psicológico que pueda ser consecuencia de la participación en este estudio.

El principal beneficio para los pacientes con CI será el contribuir a mejorar su conocimiento, habilidades y autoconfianza para la gestión de su propia salud y de la asistencia sanitaria.

CONFIDENCIALIDAD

El tratamiento, la comunicación y la cesión de los datos de carácter personal de todos los sujetos participantes se ajustará a lo dispuesto en la Ley Orgánica 3/2018, de 5 de diciembre de Protección de Datos Personales y garantía de los derechos digitales, y a la aplicación de del Reglamento (UE) 2016/679 del Parlamento europeo y del Consejo de 27 de abril de 2016 de Protección de Datos (RGPD), por lo que es importante que conozca la siguiente información:

- Además de los derechos que ya conoce (acceso, modificación, oposición y cancelación de datos) ahora también puede limitar el tratamiento de datos que sean incorrectos, solicitar una copia o que se trasladen a un tercero (portabilidad) los datos que usted ha facilitado para el estudio. Para ejercitar sus derechos, diríjase al investigador principal del estudio. Le recordamos que los datos no se pueden eliminar, aunque deje de participar en el estudio para garantizar la validez de la investigación y cumplir con los deberes legales y los requisitos de autorización de medicamentos. Así mismo tiene derecho a dirigirse a la Agencia de Protección de Datos si no quedara satisfecho/

- Tanto el Centro como el Promotor y el Investigador son responsables respectivamente del tratamiento de sus datos y se comprometen a cumplir con la normativa de protección de datos en vigor. Los datos recogidos para el estudio estarán identificados mediante un código, de manera que no se incluya información que pueda identificarle, y sólo su médico del estudio/colaboradores podrá relacionar dichos datos con usted y con su historia clínica. Por lo tanto, su identidad no será revelada a ninguna otra persona salvo a las autoridades sanitarias, cuando así lo requieran o en casos de urgencia médica. Los Comités de Ética de la Investigación, los representantes de la Autoridad Sanitaria en materia de inspección y el personal autorizado por el Promotor, únicamente podrán acceder para comprobar los datos

personales, los procedimientos del estudio clínico y el cumplimiento de las normas de buena práctica clínica (siempre manteniendo la confidencialidad de la información).

- El Investigador y el Promotor están obligados a conservar los datos recogidos para el estudio al menos hasta 25 años tras su finalización. Posteriormente, su información personal solo se conservará por el centro para el cuidado de su salud y por el promotor para otros fines de investigación científica si usted hubiera otorgado su consentimiento para ello, y si así lo permite la ley y requisitos éticos aplicables.

INFORMACIÓN ADICIONAL

Tal y como exige la ley, para participar deberá firmar y fechar el documento de consentimiento informado.

COORDINADORA DEL PROYECTO (CATALUÑA):
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INVESTIGADORA PRINCIPAL (MADRID):
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CONSENTIMIENTO INFORMADO PARA PACIENTES

Yo (nombre y apellidos)

.....

He leído la hoja de información que se me ha entregado.
He podido hacer preguntas sobre el estudio.
He recibido suficiente información sobre el estudio.
He hablado con:

.....

Comprendo que mi participación es voluntaria.
Comprendo que puedo retirarme del estudio:

1º Cuando quiera
2º Sin tener que dar explicaciones.
3º Sin que esto repercuta en mis cuidados médicos.

- Presto libremente mi conformidad para participar en el estudio y doy mi consentimiento para el acceso y utilización de mis datos en las condiciones detalladas en la hoja de información.

Nombre del participante: **Nombre del investigador**:

Fecha: **Fecha**:

Firma: **Firma**:

Additional file 2. SPIRIT checklist (49)

Section / item	Item No	Description	Page
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	7
	2b	All items from the World Health Organization Trial Registration Data Set	7
Protocol version	3	Date and version identifier	7
Funding	4	Sources and types of financial, material, and other support	27
Roles and responsibilities	5a	Name, affiliations, and roles of protocol contributors	1-5, 26
	5b	Name and contact information for the trial sponsor	5
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	27
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	16-17
Introduction			
Background	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	9,10
	6b	Explanation for choice of comparators	9,10
Objectives	7	Specific objectives or hypotheses	10
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	10
Methods			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	10
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	10-11

Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	11-12
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	14
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	11-12
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	11-12
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	12-14
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see fig 1[f1])	15, 28-30
Sample size	14	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see fig 1[f1])	15, 28-30
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	15
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers) and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	16
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	16
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	16

Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts) and how	16
	17b	If blinded, circumstances under which unblinding is permissible and procedure for revealing a participant's allocated intervention during the trial	16
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	12-14
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	12-14
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	16
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	17,18
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	17,18
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	17,18
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	16-17
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	16-17
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	15
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	16-17
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	18,19
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to	18,19

		relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	18,19
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	18,19
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	18,19
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	27
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	16-17
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	18,19
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	18,19
	31b	Authorship eligibility guidelines and any intended use of professional writers	18,19
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	18,19
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	31-35
	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	NA

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Effectiveness and cost-effectiveness of a virtual community of practice to improve the empowerment of patients with ischaemic heart disease: study protocol of a randomised controlled trial.

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TITLE

Effectiveness and cost-effectiveness of a virtual community of practice to improve the empowerment of patients with ischaemic heart disease: study protocol of a randomised controlled trial.

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ABSTRACT

Introduction

Virtual Communities of Practice (VCoP) or knowledge-sharing virtual communities offer ubiquitous access to information and exchange possibilities for people in similar situations, which might be especially valuable for the self-management of patients with chronic diseases. In view of the scarce evidence on the clinical and economic impact of these interventions on chronic conditions, we aim to evaluate the effectiveness and cost-effectiveness of a VCoP in the improvement of the activation and other patient empowerment measures in patients with ischemic heart disease (IHD).

Methods and analysis

A pragmatic randomised controlled trial will be performed in Catalonia, Madrid and Canary Islands, Spain. Two hundred fifty patients with a recent diagnosis of IHD attending the participating centres will be selected and randomised to intervention or control group. The intervention group will be offered participation for 12 months in a VCoP based on a gamified web 2.0 platform where there is interaction with other patients and a multidisciplinary professional team. Intervention and control groups will receive usual care. The primary outcome will be measured with the Patient Activation Measure questionnaire at baseline, 6, 12 and 18 months. Secondary outcomes will include: clinical variables; knowledge (Questionnaire of Cardiovascular Risk Factors), attitudes (Self-efficacy Managing Chronic Disease Scale), adherence to Mediterranean diet (Mediterranean Diet Questionnaire), level of physical activity (International Physical Activity Questionnaire), depression (Patient Health Questionnaire), anxiety (Hospital Anxiety Scale-A), medication adherence (Adherence to Refill Medication Scale), quality of life (EQ-5D-5L) and health resources use. Data will be collected from self-reported questionnaires and electronic medical records.

Ethics and dissemination

The trial was approved by Clinical Research Ethics Committee of Gregorio Marañón University Hospital in Madrid, Nuestra Señora de Candelaria University Hospital in Santa Cruz de Tenerife and IDIAP Jordi Gol in Barcelona. The results will be disseminated through workshops, policy briefs, peer-reviewed publications, local/international conferences.

Registration

ClinicalTrials.gov Identifier: NCT03959631

Strengths and limitations of this study

- We will experimentally test an innovative learning intervention based on a VCoP for patient empowerment, for which the literature lacks experimental evaluations.
- VCoP can enhance communication between community members in different geographic locations and even from different time zones.
- Participation rate can be low as similar experiences have shown; we will include the active role of a community manager, weekly emails as reminders and a gamified competitive score system to boost participation.
- Since all randomised patients will be required a minimum level of digital literacy so, the results could not be generalized to all patients.
- Patients belonging to the control group and intervention group could receive different type of self-management support depending on the centres where the care is provided.

INTRODUCTION

In Western countries, ischemic heart disease (IHD) is a major public concern as, and although mortality from IHD has been significantly reduced since 2000, it remains as a leading cause of death (50.6 deaths / 100,000 inhabitants in Spain and 106.6 deaths / 100,000 inhabitants in the United States in 2016) (1). In Spain 32,325 people died from IHD in 2017, according to the National Institute of Statistics (2). Patients with IHD may have a stable disease or an acute coronary syndrome, which could present with or without ST segment elevation. In addition, some patients may have left ventricular dysfunction and heart failure (3–5).

For the treatment of IHD, in addition to the pharmacological treatment and, if necessary, interventional procedures, it is essential to manage cardiovascular risk factors such as smoking cessation, blood pressure, lipids and diabetes control, adherence to a Mediterranean diet, active lifestyle and prevent obesity. Moreover, for the secondary prevention of IHD, cardiac rehabilitation programs are beneficial for patients, improving exercise capacity, quality of life and psychological well-being (6–8). The active role of the patient is crucial along with the support of health care providers to achieve a successful secondary prevention of IHD.

The empowerment and self-management of patients with chronic conditions is becoming one of the main objectives in health care, especially in primary care (PC). The European EMPATHiE project (9) defines the empowered patient as one who "has control over the management of the conditions of their daily life, actively tries to improve his/her quality of life and has the necessary knowledge, skills, attitudes and self-perception to adjust his/her behaviour and work in partnership with others when necessary, to achieve optimal well-being".

One of the domains included in patient empowerment is the level of patient activation. Patient activation incorporates a combination of knowledge about the illness, ability and self-confidence in the management of the medical conditions (10). It is associated with healthy behaviours, good chronic disease metrics, and reduced morbidity and unplanned hospitalizations (11–15).

Interventions aimed at empowerment are intended to provide patients (and their informal caregivers, when appropriate) with the ability to participate in decisions related to their illness to the extent they wish, develop self-confidence, self-esteem and skills to face the physical, emotional and social impact of the disease in their daily lives (16,17).

Virtual Communities of Practice (VCoP) offer ubiquitous access to information and exchange possibilities for people in similar situations, which is especially valuable in patients with chronic diseases. A CoP is a group of individuals who participate in a common activity and experience and create a shared identity and deepen their knowledge and experience in the area through a continuous interaction that strengthens their relationships (18). In this context, a group of patients with the same illness such as IHD, could benefit from an intervention of these characteristics where they can share resources and information in addition to having the possibility of receiving peer and professional support.

There is little research on the effect of VCoP in terms of their clinical and economic impact and on the empowerment of patients with chronic diseases, especially with IHD (19,20). We propose to address this gap and, thus, present the protocol of a randomised controlled trial, which mainly aims to evaluate the effectiveness and cost-effectiveness of a VCoP to improve the activation and other measures related with patient empowerment in patients with IHD.

METHODS AND ANALYSIS

This protocol has been prepared in accordance with the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) checklist (Additional file 1) (21).

[About here link to Additional file 1 on SPIRIT checklist].

Study design

We plan a pragmatic randomised controlled multicentre trial (*e*-mpodera[2]), with two parallel arms and 18-month follow-up.

Study setting

The setting of the intervention will be a virtual setting. Usual care will be provided at primary care practices (PCPs) and outpatient specialized clinics in Catalonia, Madrid and Canary Islands in Spain.

Eligibility criteria

Patients with a recent diagnosis of IHD will be screened for the following eligibility criteria:

Inclusion criteria

Age ≥ 18 years; active diagnosis in the electronic medical record (EMR) of IHD (ICPC-2 codes K74-76; or ICD-9 codes 410, 411, 411.8, 413, 414 y 414.9) in the year prior to inclusion in the study; Internet at home or Smartphone; be able to follow the requirements of the study (e.g. digital literacy); have signed the informed consent (Additional file 2).

[About here link to Additional file 2 on Informed consent].

Exclusion criteria

Institutionalized, terminal illness, physical or mental disability that limit the ability to answer the questionnaires or when telephone / email contact is not available in the PCPs/hospitals' databases.

Interventions

VCoP group

"*e*-mpodera[2]" is a gamified VCoP on a web 2.0 platform based on the exchange of experiences and knowledge through participatory learning (22). It will provide educational, playful elements and tools that will facilitate the learning and transfer of knowledge and attitudes among patients with IHD and with health care professionals. The structure and components will be designed according to the needs and specifications of patients with IHD recruited in an earlier stage using a co-creation methodology with face-to-face sessions and virtual activities (forums and interactions) that incorporated a personalized itinerary – Patient Journey Map - (published elsewhere) and with the use of various types of content including readings, resources, videos, games and virtual sessions (22).

Patients will have access to multidisciplinary professional support as needed and according to what was identified in the content-design stage (published elsewhere) will potentially include general practitioners, cardiologists, psychologists, self-care and self-management specialists, nutritionist and others as necessary. Various thematic areas related to the empowerment of patients and self-care of IHD will be progressively covered: health competence, self-efficacy and activation improvement, behavioural changes, lifestyle / signs / symptoms monitoring, technical skills, chronic disease acceptance and shared decision-making. Special emphasis will be given to the changes recommended by European Guidelines (23) for self-management of IHD including monitoring changes in symptoms, stress management, mental health and adherence to medication, diet, exercise plans, sodium cholesterol, and alcohol restriction and tobacco abstinence. The active role of a community manager, weekly emails as reminders and a gamified competitive score system will boost participation**.**

Usual care group

Patients allocated to both the intervention and the control group will continue with their usual self- and professional care according to the local guidelines (3–5).

Outcomes measures

Primary outcome

The primary outcome will be the patient activation level using the Patient Activation Measure (PAM) questionnaire that assesses activation in patients with chronic diseases (12). The questionnaire consists of 13 items that assesses knowledge, skills and confidence of people for self-care, measured by a Likert 1-4 scale with a total score between 0 and 100 (100 identifies the patients with the highest level of activation). The Spanish translated version has been validated in patients with chronic diseases and has demonstrated a similar behaviour to the original instrument with good validity and reliability properties (24). It has been used in previous studies by this research team (25).

Secondary outcomes

For the effectiveness of the VCoP, we will record the following secondary measures:

- Clinical variables such as body mass index, lipid profile (HDL-C, LDL-C), smoking status, number and frequency of angina episodes will be collected through researcher developed online questionnaire that will be fulfilled by health care professionals combined with information from the EMR.
- Knowledge about the disease will be assessed through a self-administered online questionnaire based on the Questionnaire of Cardiovascular Risk Factors (Q-FARC) (26–28), previously translated from the English version and adapted to the Spanish population.
- Patients' attitudes to self-care will be evaluated using the self-administered Self-efficacy Managing Chronic Disease Scale (SMCDS) (29), translated into Spanish (30) and used in patients with heart failure (31).
- Adherence to Mediterranean diet will be assessed with the Mediterranean diet questionnaire (32), validated in the Spanish population in the PREDIMED study (33–35).
- Physical activity will be measured using the International Physical Activity Questionnaire (IPAQ), translated and adapted to the Spanish language (36). Patients will be classified into three categories (low, medium and high) according to the index of physical activity (product of the intensity - in METS - by the frequency,) and the duration of the activity.
- Depressive disorders will be detected by the Patient Health Questionnaire-9 (PHQ-9) (37), validated in Spanish with similar behaviour to the original and good acceptance (38).
- Anxiety will be assessed using the Hospital Anxiety and Depression Scale (HADS-A scale) (39), a 14-item questionnaire validated in PC in Spain (40,41), with special interest and usefulness in the context of PC. It is a measure composed of two sub-scales (HAD-A: anxiety and HAD-D: depression), of 7 items each that are scored from 0 to 3. The authors recommend a threshold of 8 points to detect possible cases of anxiety. One of the main virtues of this tool is the suppression of somatic symptoms. However, in patients with IHD it underestimates people

with depression (42), while the sub-scale HADS-A has good specificity and predictive value for measuring anxiety in this PC (43).

- Adherence to medication will be assessed with the Adherence Refill and Medication Scale (ARMS-e) (44), validated in Spain and used to measure adherence to medication in patients with chronic diseases. It consists of 12 questions and there is no cut-off point, the lower the score, the better the adherence. To quantify adherence, a value of 1 to 4 (never, sometimes, almost always or always) is assigned to each of the responses according to a Likert-type scale.
- Quality of life related to health (HRQoL) will be described and assessed with the EQ-5D-5L index (45,46), a generic and standardized instrument developed by the EuroQoL Group, and prepared in several languages, including Spanish, and used in PC (47). It relates the HRQoL with the amount of life and offers a score for the gains in health, the Quality Adjusted Life Year (QALY). The descriptive EQ-5D-5L system comprises 5 dimensions (mobility, personal care, daily activities, pain / discomfort and anxiety / depression).

Explanatory and adjustment variables

- Sociodemographic: age, sex, nationality, Autonomous Community of residence (Catalonia, Madrid or Canary Islands), marital status (married/partner, single, separated/divorced, widowed), living alone (yes/no), educational level (incomplete primary education, complete primary education, secondary education, university or equivalent studies), income level and employment status (48).
- Morbidity related: type of IHD (stable angina, unstable angina, MI), duration of IHD (months), current diagnosis of heart failure in EMR (K86), left ventricular ejection fraction ($\leq$ 30%, 30-35%, 35-45%, >45%), NYHA class (I-IV), number and description of chronic concomitant diseases (49), pharmacological treatment (acetylsalicylic acid or clopidogrel/ticagrelor/prasugrel, beta-blockers, statins, angiotensin-converting enzyme (ACE) inhibitors, angiotensin II receptor blockers, other treatments), cardiac catheterization (yes/no)

and participation in a cardiac rehabilitation program before and during the study period (yes/no).

- Use of health care resources: primary care (PC) visits, visits to the emergency department, visits to specialists, number of hospitalizations, lengths of stay, prescribed medications, use of diagnostic tests.
- Loss of productivity: self-administered questionnaire about work absences related to the illness.
- Use of the VCoP: number of logins into the platform.

This information will be collected online from a patient self-reported questionnaire that the research team will elaborate combined with information from the EMR. VCoP use data will be collected through the platform database.

Adverse events

All significant adverse events as well as unintended consequences for each group will be collected and described by the site researcher, nominated for each PCP and hospital, and reported to the core team. A special form to report trial-related adverse events has been developed and distributed.

Participant timeline

Primary and secondary outcome measures will be collected before the start of the VCoP intervention and at 6, 12 and 18 months. See Table 1.

[About here: Table 1 on Schedule of enrolment, interventions, and assessments (SPIRIT checklist)].

Sample size

Assuming an alpha error of 0.05 and power of 80%, the necessary number of patients to detect, by means of independent two-sample t-test, an average minimal important difference of 4 points (SD 10) in the PAM questionnaire (12,24) between the intervention and usual care group, is 200 patients (100 per arm). Assuming a 20% loss to follow up, the required sample increases to 250 (125 per arm).

Recruitment

Patient recruitment will be organized on each Autonomous Community (Catalonia, Madrid or Canary Islands). The recruitment will be supported by informative meetings with directors and health care professionals (general practitioners, nurses, cardiologists) from the participating centres. In these meetings, a 10-minute presentation describing the study aim, planned time frame and tasks to be carried out by health care professionals, expected resources utilization and funding procedures will be detailed. Patients that fulfil inclusion criteria will be actively encouraged by their health care professionals to participate by providing information about the trial and collecting their informed consent and contact details (e.g. phone number / email). The research team will invite potential participants via phone and mail to access the "*e*-mpodera²" platform where they will be provided with a unique registration code (Figure 1). Patients will be consecutively included in the study; recruitment will be continuous until the sample size is reached.

[About here: Figure 1 on Flow of participants].

Allocation and blinding

Two hundred and fifty patients will be randomly assigned to the intervention (VCoP) or control group. The randomisation, stratified by centre, will be central and automatically performed by the online "*e*-mpodera²" platform and the assigned group will be communicated to the patient once he or she has entered the platform and completed baseline assessment (Figure 1). Lack of knowledge of the randomisation sequence by the professionals who participate in the recruitment of patients will therefore be ensured. The intervention group will be taken directly to the registration page of "*e*-mpodera²" VCoP, where they will receive a personalized message to welcome them into the platform. To warrant patient participation and cooperation, this type of intervention cannot be blinded to patients. Data analysis will be blinded to the assignment of the intervention.

Data management

In order to maintain participant confidentiality all information will be stored with anonymized ID code numbers. The ID code numbers will be unrelated to participants' identifiers, except in a central file with the participants' contact details. All data will be stored on an electronic database management system located on a secure server with password-controlled access provided for research data collection. Databases will be designed to avoid downloading inappropriate values for every variable. Trial monitoring will be the responsibility of the core research team in charge of all quality control activities, assessing adherence to the trial protocol: timely work plan execution and comprehensiveness of data acquisition and data quality.

The Research Ethics Committees, the representatives of the Health Authority in matters of inspection and the personnel authorized by the Promoter, may only access to check personal data, clinical study procedures and compliance with the rules of good clinical practice (always maintaining the confidentiality of information).

Statistical analysis

Sociodemographic and clinical baseline variables for both groups will be analysed by descriptive methods (mean (SD), median (range), n (%)). The VCoP effect on the primary and secondary outcomes will be examined by means of multilevel linear regression, with the intervention, measurement time (0, 6, 12, 18 months) and their interaction as fixed effects (along with other potential covariates), random intercepts for patients and GP, and random slope for time, to account for within-subject correlations. We will also analyse the three-way interaction intervention x time x centre, since usual care could vary between centres, leading to differential intervention effects. We expect to recruit a sufficient number of GP to allow their inclusion in the model as a random intercept, but anyway we will perform a sensitivity analysis excluding this component. Between-group differences at each time-point will be compared by means of Wald's χ^2 test.

We will perform the analyses on an intention-to-treat basis (a sensitivity analysis on the per-protocol population will be also performed). Multiple imputation will be used for missing data, if

applicable (Markov Chain Monte Carlo multivariate imputation algorithm, with 10 imputations per variable). Analyses will be carried out with the statistical software R 4.0.2 http://www.R-project.org/.

Cost-effectiveness analysis of the VCoP (6, 12 and 18 months).

We will carry out an economic evaluation in which the costs and the results of the VCoP will be compared to the usual care following the recommendations of the guidelines for the management of patients with IHD (3–5), during the period of the clinical trial. The accepted analytical methods by the scientific community will be followed (50). The analysis will take both the perspective of the National Health System and of the social perspective. Therefore, direct healthcare costs and indirect costs will be included. The direct costs per patient will be calculated based on the use of healthcare resources, and the indirect costs will be estimated focusing on productivity losses due to IHD, applying the human capital approach. In addition to including the short-term costs (development and implementation of the VCoP), the costs observed during the follow-up will be included. The use of resources will be obtained from a patient self-reported questionnaire described in the outcome section. In addition, information about work absences related to the illness will be requested. The classic costs estimation approach will be followed multiplying the use of resources by their unit cost. The unit costs will be obtained from the eHealth cost database (*Oblikue Consulting*) and from public sources such as rates and PVP. The main outcome measure will be the incremental cost per gained QALY. The utilities for the estimation of the QALYs will be obtained through the EQ-5D-5L questionnaire (45) that will be completed by the patient at the beginning of the study and at each follow-up visit. Results of the cost-effectiveness analysis will be summarized as the incremental cost-effectiveness ratio (ICER). ICER is the ratio of the differences in costs to the differences in observed effects. Non-parametric methods based on bootstrap simulations will be used to calculate confidence intervals in the ICER. The same nonparametric methods will be used to calculate the acceptability curve that represents the probability that each choice will be cost-effective for different cost-effectiveness thresholds. The willingness-to-pay

threshold is defined at Euro 25,000/QALY on the basis of the values most recently reported in the Spanish literature (51). Finally, deterministic sensitivity analyses (one, two or several ways) will be carried out in order to assess the impact of the parameters on the cost-effectiveness results of the VCoP.

Patient and public involvement

This protocol was developed without patient or public involvement. A group of patients with IHD will actively participate in a content-design previous stage using a co-creation methodology with face-to-face sessions and virtual activities.

ETHICS AND DISSEMINATION

The study is registered on ClinicalTrials.gov. code NCT03959631 (https://clinicaltrials.gov/ct2/show/NCT03959631?recrs=b&type=Intr&cond=coronary+heart+disease&age=1&draw=2). Informed consent will be obtained from each participant before randomisation. The project received ethics approval from the local Committees at each participating Autonomous Community: Clinical Research Ethics Committee of Gregorio Marañón University Hospital in Madrid, Nuestra Señora de Candelaria University Hospital in Santa Cruz de Tenerife and from the coordinating centre IDIAP Jordi Gol in Barcelona (19/053-P). Patients will be personally informed by their physicians or nurses about the study and the possibility to participate during a programmed consultation. They will receive written information of the proposed research project, including information regarding the aims of the project, the duration of the participants' involvement, the expected benefits to the participant and the procedures involved in the participation. Recruiters will emphasize that enrolment in the study is voluntary and that participants can withdraw at any moment of the project and that any decision they take in this respect will have no bearing on the medical care received. Once patients have signed the written informed consent, a researcher from the "*e*-mpodera²" team will contact them via phone and/ or mail to provide further information along with the necessary data (username and password) to

login into the online platform. Additionally, recruiters will highlight that information generated by the study will be published, but no identification details will be divulged. Patients and health care providers will be informed of whom to contact in case of any query and research staff will be available to answer questions.

We will prepare presentations to disseminate the study findings to healthcare stakeholders and patients, and at relevant national and international conferences. We aim to publish the results of the trial in peer-reviewed journals.

TRIAL STATUS

The recruitment of patients in each region will start in September 2020. The estimated end date of the recruitment for this study is December 2020.

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CONTRIBUTORS

AIG wrote the initial draft of the protocol. CO is the guarantor of the trial. AIG, CO, LP, DK, VP and MB conceived the project. SG, AR and CV provided the methodological guidance. AT, VR, ATC, JMR, JCR, SD, LM, JGG, NVC, AR, JCdC, JMB, MET, MM, YdR and ABR are co-supervisors of this project, providing advice at all stages of the development of the protocol, and contributed to the revision of the manuscript. All authors read and approved the final manuscript.

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DISCLAIMER

The funder had no role in developing the protocol or obtaining the results for this review.

COMPETING INTERES

None declared

DATA SHARING

No additional data available

WORD COUNT

3,3423

Table 1. Schedule of enrolment, interventions, and assessments (SPIRIT checklist)

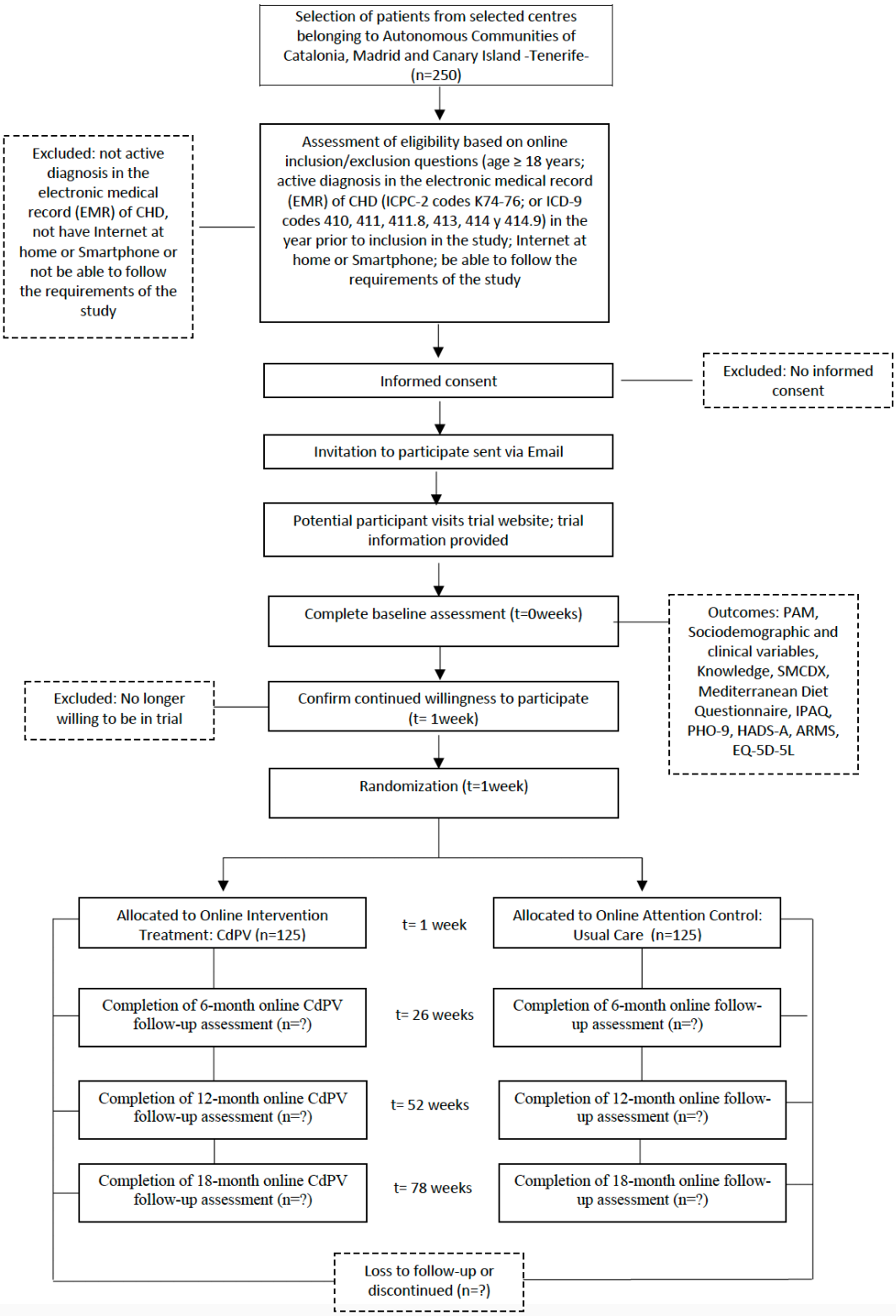
	STUDY PERIOD				
	Pre-allocation		Post-allocation		Close-out
TIMEPOINT	**Enrolment**	**Baseline**	**6 months**	**12 months**	**18 months**
Eligibility screen	X				
Informed consent	X				
INTERVENTIONS:					
VCoP					
Usual care					
ASSESSMENTS:					
PAM		X	X	X	X
Sociodemographic and clinical variables		X	X*	X*	X*
Knowledge		X	X	X	X
SMCDX		X	X	X	X
Mediterranean Diet Questionnaire		X	X	X	X
IPAQ		X	X	X	X
PHQ-9		X	X	X	X
HADS-A		X	X	X	X
ARMS-e		X	X	X	X
EQ-5D-5L		X	X	X	X
Use of resources			X	X	X
Use of VCoP					
Adverse events					

HADS = Hospital Anxiety and Depression Scale; IPAQ = International Physical Activity Questionnaire; ARMS-e = Adherence Refill and Medication Scale; PAM = Patient Activation

Measure; PHQ-9 = Patient Health Questionnaire; SMCDS = Self-efficacy Managing Chronic Disease Scale; VCoP = Virtual Community of Practice.
*Follow-up of just clinical variables

Figure 1. Flow of participants

Figure 1. Flow of participants



Additional file 1. SPIRIT checklist

Section / item	Item No	Description	Page
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	7
	2b	All items from the World Health Organization Trial Registration Data Set	7
Protocol version	3	Date and version identifier	7
Funding	4	Sources and types of financial, material, and other support	27
Roles and responsibilities	5a	Name, affiliations, and roles of protocol contributors	1-5, 26
	5b	Name and contact information for the trial sponsor	5
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	27
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	16-17
Introduction			
Background	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	9,10
	6b	Explanation for choice of comparators	9,10
Objectives	7	Specific objectives or hypotheses	10
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	10
Methods			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	10
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	10-11

Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	11-12
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	14
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	11-12
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	11-12
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	12-14
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see fig 1[f1])	15, 28-30
Sample size	14	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see fig 1[f1])	15, 28-30
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	15
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers) and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	16
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	16
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	16

Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts) and how	16
	17b	If blinded, circumstances under which unblinding is permissible and procedure for revealing a participant's allocated intervention during the trial	16
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	12-14
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	12-14
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	16
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	17,18
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	17,18
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	17,18
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	16-17
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	16-17
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	15
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	16-17
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	18,19
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to	18,19

		relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	18,19
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	18,19
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	18,19
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	27
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	16-17
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	18,19
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	18,19
	31b	Authorship eligibility guidelines and any intended use of professional writers	18,19
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	18,19
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	31-35
	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	NA

Additional file 2. Informed consent

HOJA DE INFORMACIÓN AL PACIENTE

FASE ENSAYO CLÍNICO

INTRODUCCIÓN

Estimado/a Sr/a:

Le comunicamos que se está desarrollando la puesta en marcha del ensayo clínico denominado **"Efectividad y coste-efectividad de una intervención virtual (Comunidad de Práctica) para la mejora del empoderamiento de pacientes con cardiopatía isquémica en atención primaria: ensayo controlado aleatorizado por conglomerados" (Cataluña: PI18/01404/, Madrid: PI18/01397, Canarias: PI18/01333).**

Este estudio ha sido aprobado por los Comités Éticos de los centros participantes de acuerdo con la legislación vigente, la Ley Orgánica 3/2018, de 5 de diciembre de Protección de Datos Personales y garantía de los derechos digitales, y a la aplicación del Reglamento (UE) 2016/679 del Parlamento europeo y del Consejo de 27 de abril de 2016 de Protección de Datos (RGPD) por el que se regula este tipo de estudios.

Nuestra intención es tan solo que usted reciba la información correcta y suficiente para que pueda evaluar y juzgar si quiere o no participar en este estudio. Para ello lea esta hoja informativa con atención y nosotros le aclararemos las dudas que le puedan surgir después de la explicación. Además, puede consultar con las personas que considere oportuno.

PARTICIPACIÓN VOLUNTARIA

Debe saber que su participación en este estudio es voluntaria y que puede decidir no participar o cambiar su decisión y retirar el consentimiento en cualquier momento, sin que por ello se altere la relación con su médico ni se produzca perjuicio alguno en su tratamiento.

¿Quiénes son los investigadores?

El equipo de investigación está formado por un equipo multidisciplinar (medicina, psicología, estadística y evaluación de servicios sanitarios, médicos de familia, enfermeras, cardiólogos) cuyos miembros pertenecen a las siguientes instituciones:

Fundación Avedis Donabedian, Gerencia Asistencial de Atención Primaria (GAAP) del Servicio Madrileño de Salud y Servicio de Evaluación del Servicio Canario de la Salud (SESCS).

Este proyecto ha surgido de una iniciativa colaborativa en el marco de la Red de Investigación en Servicios de Salud en Enfermedades Crónicas (REDISSEC).

DESCRIPCIÓN GENERAL DEL ESTUDIO

¿Por qué se hace este estudio?

Para evaluar la efectividad de una de una Comunidad de Práctica (CdP) virtual dirigida a pacientes con cardiopatía isquémica (CI) para mejorar su conocimiento, habilidades y autoconfianza para gestionar su propia salud y de la asistencia sanitaria que recibe.

¿Quién puede participar?

Si usted es mayor de 18 años, tiene cardiopatía isquémica, dispone de internet en su hogar y/o Smartphone.

Procedimiento del estudio:

Existirán dos grupos de estudio, Grupo de intervención (GI) y Grupo Control (GC), y a los pacientes se les asignará uno u otro al azar. En el caso de que usted quisiera participar en el estudio podría estar en cualquiera de los 2 grupos.

Si usted desea participar, ¿en qué consiste su participación?

La duración del estudio será de 18 meses. Al comienzo del estudio, a los 6, 12 y 18 meses, los participantes cumplimentarán unos cuestionarios online sobre aspectos relacionados con el nivel de activación de cada participante en las decisiones relacionadas con su salud (cuestionario PAM), el conocimiento de la enfermedad, la actitud hacia la enfermedad, la adherencia a la dieta mediterránea, la actividad física y algunos cuestionarios relacionados con variables psicológicas. Cumplimentar estos cuestionarios le llevará aproximadamente 30 minutos.

Si de forma aleatoria cae en el Grupo de intervención, se le ofrecerá participar durante 18 meses en una Comunidad de Práctica Virtual (CdPv) basada en una plataforma web 2.0. Se pondrá a disposición un enlace (vía email) para registrarse e iniciar la participación voluntaria.

Dentro de esta CdPv usted podrá disponer de elementos educativos, lúdicos y herramientas para facilitar el aprendizaje y la transferencia de conocimientos y de sus actitudes. Además, se trabajarán diversas temáticas relacionadas con: competencias en salud, técnicas de

autoeficacia, estilos de vida, aceptación de la enfermedad crónica y toma de decisiones compartida, dieta, planes de ejercicio, gestión del estrés, etc.

Si de forma aleatoria cae en el Grupo Control, usted seguirá los cuidados y atención propias de la práctica clínica habitual.

RIESGOS Y BENEFICIOS DE LA PARTICIPACIÓN EN ESTE ESTUDIO

No se prevé ningún tipo de riesgo físico ni psicológico que pueda ser consecuencia de la participación en este estudio.

El principal beneficio para los pacientes con CI será el contribuir a mejorar su conocimiento, habilidades y autoconfianza para la gestión de su propia salud y de la asistencia sanitaria.

CONFIDENCIALIDAD

El tratamiento, la comunicación y la cesión de los datos de carácter personal de todos los sujetos participantes se ajustará a lo dispuesto en la Ley Orgánica 3/2018, de 5 de diciembre de Protección de Datos Personales y garantía de los derechos digitales, y a la aplicación de del Reglamento (UE) 2016/679 del Parlamento europeo y del Consejo de 27 de abril de 2016 de Protección de Datos (RGPD), por lo que es importante que conozca la siguiente información:

- Además de los derechos que ya conoce (acceso, modificación, oposición y cancelación de datos) ahora también puede limitar el tratamiento de datos que sean incorrectos, solicitar una copia o que se trasladen a un tercero (portabilidad) los datos que usted ha facilitado para el estudio. Para ejercitar sus derechos, diríjase al investigador principal del estudio. Le recordamos que los datos no se pueden eliminar, aunque deje de participar en el estudio para garantizar la validez de la investigación y cumplir con los deberes legales y los requisitos de autorización de medicamentos. Así mismo tiene derecho a dirigirse a la Agencia de Protección de Datos si no quedara satisfecho/

- Tanto el Centro como el Promotor y el Investigador son responsables respectivamente del tratamiento de sus datos y se comprometen a cumplir con la normativa de protección de datos en vigor. Los datos recogidos para el estudio estarán identificados mediante un código, de manera que no se incluya información que pueda identificarle, y sólo su médico del estudio/colaboradores podrá relacionar dichos datos con usted y con su historia clínica. Por lo tanto, su identidad no será revelada a ninguna otra persona salvo a las autoridades sanitarias, cuando así lo requieran o en casos de urgencia médica. Los Comités de Ética de la Investigación, los representantes de la Autoridad Sanitaria en materia de inspección y el personal autorizado por el Promotor, únicamente podrán acceder para comprobar los datos

personales, los procedimientos del estudio clínico y el cumplimiento de las normas de buena práctica clínica (siempre manteniendo la confidencialidad de la información).

- El Investigador y el Promotor están obligados a conservar los datos recogidos para el estudio al menos hasta 25 años tras su finalización. Posteriormente, su información personal solo se conservará por el centro para el cuidado de su salud y por el promotor para otros fines de investigación científica si usted hubiera otorgado su consentimiento para ello, y si así lo permite la ley y requisitos éticos aplicables.

INFORMACIÓN ADICIONAL

Tal y como exige la ley, para participar deberá firmar y fechar el documento de consentimiento informado.

COORDINADORA DEL PROYECTO (CATALUÑA):
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CONSENTIMIENTO INFORMADO PARA PACIENTES

Yo (nombre y apellidos)

.....

He leído la hoja de información que se me ha entregado.
He podido hacer preguntas sobre el estudio.
He recibido suficiente información sobre el estudio.
He hablado con:

.....

Comprendo que mi participación es voluntaria.
Comprendo que puedo retirarme del estudio:

1º Cuando quiera
2º Sin tener que dar explicaciones.
3º Sin que esto repercuta en mis cuidados médicos.

- Presto libremente mi conformidad para participar en el estudio y doy mi consentimiento para el acceso y utilización de mis datos en las condiciones detalladas en la hoja de información.

Nombre del participante: **Nombre del investigador**:

Fecha: **Fecha**:

Firma: **Firma**:

BMJ Open

Effectiveness and cost-effectiveness of a virtual community of practice to improve the empowerment of patients with ischaemic heart disease: study protocol of a randomised controlled trial.

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TITLE

Effectiveness and cost-effectiveness of a virtual community of practice to improve the empowerment of patients with ischaemic heart disease: study protocol of a randomised controlled trial.

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ABSTRACT

Introduction

Virtual Communities of Practice (VCoP) or knowledge-sharing virtual communities offer ubiquitous access to information and exchange possibilities for people in similar situations, which might be especially valuable for the self-management of patients with chronic diseases. In view of the scarce evidence on the clinical and economic impact of these interventions on chronic conditions, we aim to evaluate the effectiveness and cost-effectiveness of a VCoP in the improvement of the activation and other patient empowerment measures in patients with ischemic heart disease (IHD).

Methods and analysis

A pragmatic randomised controlled trial will be performed in Catalonia, Madrid and Canary Islands, Spain. Two hundred fifty patients with a recent diagnosis of IHD attending the participating centres will be selected and randomised to intervention or control group. The intervention group will be offered participation for 12 months in a VCoP based on a gamified web 2.0 platform where there is interaction with other patients and a multidisciplinary professional team. Intervention and control groups will receive usual care. The primary outcome will be measured with the Patient Activation Measure questionnaire at baseline, 6, 12 and 18 months. Secondary outcomes will include: clinical variables; knowledge (Questionnaire of Cardiovascular Risk Factors), attitudes (Self-efficacy Managing Chronic Disease Scale), adherence to Mediterranean diet (Mediterranean Diet Questionnaire), level of physical activity (International Physical Activity Questionnaire), depression (Patient Health Questionnaire), anxiety (Hospital Anxiety Scale-A), medication adherence (Adherence to Refill Medication Scale), quality of life (EQ-5D-5L) and health resources use. Data will be collected from self-reported questionnaires and electronic medical records.

Ethics and dissemination

The trial was approved by Clinical Research Ethics Committee of Gregorio Marañón University Hospital in Madrid, Nuestra Señora de Candelaria University Hospital in Santa Cruz de Tenerife and IDIAP Jordi Gol in Barcelona. The results will be disseminated through workshops, policy briefs, peer-reviewed publications, local/international conferences.

Registration

ClinicalTrials.gov Identifier: NCT03959631

Strengths and limitations of this study

- We will experimentally test an innovative learning intervention based on a VCoP for patient empowerment, for which the literature lacks experimental evaluations.
- VCoP can enhance communication between community members in different geographic locations and even from different time zones.
- Participation rate can be low as similar experiences have shown; we will include the active role of a community manager, weekly emails as reminders and a gamified competitive score system to boost participation.
- Since all randomised patients will be required a minimum level of digital literacy so, the results could not be generalized to all patients.
- Patients belonging to the control group and intervention group could receive different type of self-management support depending on the centres where the care is provided.

INTRODUCTION

In Western countries, ischemic heart disease (IHD) is a major public concern as, and although mortality from IHD has been significantly reduced since 2000, it remains as a leading cause of death (50.6 deaths / 100,000 inhabitants in Spain and 106.6 deaths / 100,000 inhabitants in the United States in 2016) (1). In Spain 32,325 people died from IHD in 2017, according to the National Institute of Statistics (2). Patients with IHD may have a stable disease or an acute coronary syndrome, which could present with or without ST segment elevation. In addition, some patients may have left ventricular dysfunction and heart failure (3–5).

For the treatment of IHD, in addition to the pharmacological treatment and, if necessary, interventional procedures, it is essential to manage cardiovascular risk factors such as smoking cessation, blood pressure, lipids and diabetes control, adherence to a Mediterranean diet, active lifestyle and prevent obesity. Moreover, for the secondary prevention of IHD, cardiac rehabilitation programs are beneficial for patients, improving exercise capacity, quality of life and psychological well-being (6–8). The active role of the patient is crucial along with the support of health care providers to achieve a successful secondary prevention of IHD.

The empowerment and self-management of patients with chronic conditions is becoming one of the main objectives in health care, especially in primary care (PC). The European EMPATHiE project (9) defines the empowered patient as one who "has control over the management of the conditions of their daily life, actively tries to improve his/her quality of life and has the necessary knowledge, skills, attitudes and self-perception to adjust his/her behaviour and work in partnership with others when necessary, to achieve optimal well-being".

One of the domains included in patient empowerment is the level of patient activation. Patient activation incorporates a combination of knowledge about the illness, ability and self-confidence in the management of the medical conditions (10). It is associated with healthy behaviours, good chronic disease metrics, and reduced morbidity and unplanned hospitalizations (11–15).

Interventions aimed at empowerment are intended to provide patients (and their informal caregivers, when appropriate) with the ability to participate in decisions related to their illness to the extent they wish, develop self-confidence, self-esteem and skills to face the physical, emotional and social impact of the disease in their daily lives (16,17).

Virtual Communities of Practice (VCoP) offer ubiquitous access to information and exchange possibilities for people in similar situations, which is especially valuable in patients with chronic diseases. A CoP is a group of individuals who participate in a common activity and experience and create a shared identity and deepen their knowledge and experience in the area through a continuous interaction that strengthens their relationships (18). In this context, a group of patients with the same illness such as IHD, could benefit from an intervention of these characteristics where they can share resources and information in addition to having the possibility of receiving peer and professional support.

There is little research on the effect of VCoP in terms of their clinical and economic impact and on the empowerment of patients with chronic diseases, especially with IHD (19,20). We propose to address this gap and, thus, present the protocol of a randomised controlled trial, which mainly aims to evaluate the effectiveness and cost-effectiveness of a VCoP to improve the activation and other measures related with patient empowerment in patients with IHD.

METHODS AND ANALYSIS

This protocol has been prepared in accordance with the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) checklist (Additional file 1) (21).

[About here link to Additional file 1 on SPIRIT checklist].

Study design

We plan a pragmatic randomised controlled multicentre trial (*e*-mpodera[2]), with two parallel arms and 18-month follow-up.

Study setting

The setting of the intervention will be a virtual setting. Usual care will be provided at primary care practices (PCPs) and outpatient specialized clinics in Catalonia, Madrid and Canary Islands in Spain.

Eligibility criteria

Patients with a recent diagnosis of IHD will be screened for the following eligibility criteria:

Inclusion criteria

Age ≥ 18 years; active diagnosis in the electronic medical record (EMR) of IHD (ICPC-2 codes K74-76; or ICD-9 codes 410, 411, 411.8, 413, 414 y 414.9) in the year prior to inclusion in the study; Internet at home or Smartphone; be able to follow the requirements of the study (e.g. digital literacy); have signed the informed consent (Additional file 2).

[About here link to Additional file 2 on Informed consent].

Exclusion criteria

Institutionalized, terminal illness, physical or mental disability that limit the ability to answer the questionnaires or when telephone / email contact is not available in the PCPs/hospitals' databases.

Interventions

VCoP group

"*e*-mpodera[2]" is a gamified VCoP on a web 2.0 platform based on the exchange of experiences and knowledge through participatory learning (22). It will provide educational, playful elements and tools that will facilitate the learning and transfer of knowledge and attitudes among patients with IHD and with health care professionals. The structure and components will be designed according to the needs and specifications of patients with IHD recruited in an earlier stage using a co-creation methodology with face-to-face sessions and virtual activities (forums and interactions) that incorporated a personalized itinerary – Patient Journey Map - (published elsewhere) and with the use of various types of content including readings, resources, videos, games and virtual sessions (22).

Patients will have access to multidisciplinary professional support as needed and according to what was identified in the content-design stage (published elsewhere) will potentially include general practitioners, cardiologists, psychologists, self-care and self-management specialists, nutritionist and others as necessary. Various thematic areas related to the empowerment of patients and self-care of IHD will be progressively covered: health competence, self-efficacy and activation improvement, behavioural changes, lifestyle / signs / symptoms monitoring, technical skills, chronic disease acceptance and shared decision-making. Special emphasis will be given to the changes recommended by European Guidelines (23) for self-management of IHD including monitoring changes in symptoms, stress management, mental health and adherence to medication, diet, exercise plans, sodium cholesterol, and alcohol restriction and tobacco abstinence. The active role of a community manager, weekly emails as reminders and a gamified competitive score system will boost participation**.**

Usual care group

Patients allocated to both the intervention and the control group will continue with their usual self- and professional care according to the local guidelines (3–5).

Outcomes measures

Primary outcome

The primary outcome will be the patient activation level using the Patient Activation Measure (PAM) questionnaire that assesses activation in patients with chronic diseases (12). The questionnaire consists of 13 items that assesses knowledge, skills and confidence of people for self-care, measured by a Likert 1-4 scale with a total score between 0 and 100 (100 identifies the patients with the highest level of activation). The Spanish translated version has been validated in patients with chronic diseases and has demonstrated a similar behaviour to the original instrument with good validity and reliability properties (24). It has been used in previous studies by this research team (25).

Secondary outcomes

For the effectiveness of the VCoP, we will record the following secondary measures:

- Clinical variables such as body mass index, lipid profile (HDL-C, LDL-C), smoking status, number and frequency of angina episodes will be collected through researcher developed online questionnaire that will be fulfilled by health care professionals combined with information from the EMR.
- Knowledge about the disease will be assessed through a self-administered online questionnaire based on the Questionnaire of Cardiovascular Risk Factors (Q-FARC) (26–28), previously translated from the English version and adapted to the Spanish population.
- Patients' attitudes to self-care will be evaluated using the self-administered Self-efficacy Managing Chronic Disease Scale (SMCDS) (29), translated into Spanish (30) and used in patients with heart failure (31).
- Adherence to Mediterranean diet will be assessed with the Mediterranean diet questionnaire (32), validated in the Spanish population in the PREDIMED study (33–35).
- Physical activity will be measured using the International Physical Activity Questionnaire (IPAQ), translated and adapted to the Spanish language (36). Patients will be classified into three categories (low, medium and high) according to the index of physical activity (product of the intensity - in METS - by the frequency,) and the duration of the activity.
- Depressive disorders will be detected by the Patient Health Questionnaire-9 (PHQ-9) (37), validated in Spanish with similar behaviour to the original and good acceptance (38).
- Anxiety will be assessed using the Hospital Anxiety and Depression Scale (HADS-A scale) (39), a 14-item questionnaire validated in PC in Spain (40,41), with special interest and usefulness in the context of PC. It is a measure composed of two sub-scales (HAD-A: anxiety and HAD-D: depression), of 7 items each that are scored from 0 to 3. The authors recommend a threshold of 8 points to detect possible cases of anxiety. One of the main virtues of this tool is the suppression of somatic symptoms. However, in patients with IHD it underestimates people

with depression (42), while the sub-scale HADS-A has good specificity and predictive value for measuring anxiety in this PC (43).

- Adherence to medication will be assessed with the Adherence Refill and Medication Scale (ARMS-e) (44), validated in Spain and used to measure adherence to medication in patients with chronic diseases. It consists of 12 questions and there is no cut-off point, the lower the score, the better the adherence. To quantify adherence, a value of 1 to 4 (never, sometimes, almost always or always) is assigned to each of the responses according to a Likert-type scale.
- Quality of life related to health (HRQoL) will be described and assessed with the EQ-5D-5L index (45,46), a generic and standardized instrument developed by the EuroQoL Group, and prepared in several languages, including Spanish, and used in PC (47). It relates the HRQoL with the amount of life and offers a score for the gains in health, the Quality Adjusted Life Year (QALY). The descriptive EQ-5D-5L system comprises 5 dimensions (mobility, personal care, daily activities, pain / discomfort and anxiety / depression).

Explanatory and adjustment variables

- Sociodemographic: age, sex, nationality, Autonomous Community of residence (Catalonia, Madrid or Canary Islands), marital status (married/partner, single, separated/divorced, widowed), living alone (yes/no), educational level (incomplete primary education, complete primary education, secondary education, university or equivalent studies), income level and employment status (48).
- Morbidity related: type of IHD (stable angina, unstable angina, MI), duration of IHD (months), current diagnosis of heart failure in EMR (K86), left ventricular ejection fraction ($\leq$ 30%, 30-35%, 35-45%, >45%), NYHA class (I-IV), number and description of chronic concomitant diseases (49), pharmacological treatment (acetylsalicylic acid or clopidogrel/ticagrelor/prasugrel, beta-blockers, statins, angiotensin-converting enzyme (ACE) inhibitors, angiotensin II receptor blockers, other treatments), cardiac catheterization (yes/no)

and participation in a cardiac rehabilitation program before and during the study period (yes/no).

- Use of health care resources: primary care (PC) visits, visits to the emergency department, visits to specialists, number of hospitalizations, lengths of stay, prescribed medications, use of diagnostic tests.
- Loss of productivity: self-administered questionnaire about work absences related to the illness.
- Use of the VCoP: number of logins into the platform and time spent using the platform.

This information will be collected online from a patient self-reported questionnaire that the research team will elaborate combined with information from the EMR. VCoP use data will be collected through the platform database.

Adverse events

All significant adverse events as well as unintended consequences for each group will be collected and described by the site researcher, nominated for each PCP and hospital, and reported to the core team. A special form to report trial-related adverse events has been developed and distributed.

Participant timeline

Primary and secondary outcome measures will be collected before the start of the VCoP intervention and at 6, 12 and 18 months. See Table 1.

[About here: Table 1 on Schedule of enrolment, interventions, and assessments (SPIRIT checklist)].

Sample size

Assuming an alpha error of 0.05 and power of 80%, the necessary number of patients to detect, by means of independent two-sample t-test, an average minimal important difference of 4 points (SD 10) in the PAM questionnaire (12,24) between the intervention and usual care group, is 200 patients (100 per arm). Assuming a 20% loss to follow up, the required sample increases to 250 (125 per arm).

Recruitment

Patient recruitment will be organized on each Autonomous Community (Catalonia, Madrid or Canary Islands). The recruitment will be supported by informative meetings with directors and health care professionals (general practitioners, nurses, cardiologists) from the participating centres. In these meetings, a 10-minute presentation describing the study aim, planned time frame and tasks to be carried out by health care professionals, expected resources utilization and funding procedures will be detailed. Patients that fulfil inclusion criteria will be actively encouraged by their health care professionals to participate by providing information about the trial and collecting their informed consent and contact details (e.g. phone number / email). The research team will invite potential participants via phone and mail to access the "*e*-mpodera²" platform where they will be provided with a unique registration code (Figure 1). Patients will be consecutively included in the study; recruitment will be continuous until the sample size is reached.

[About here: Figure 1 on Flow of participants].

Allocation and blinding

Two hundred and fifty patients will be randomly assigned to the intervention (VCoP) or control group. The randomisation, stratified by centre, will be central and automatically performed by the online "*e*-mpodera²" platform and the assigned group will be communicated to the patient once he or she has entered the platform and completed baseline assessment (Figure 1). Lack of knowledge of the randomisation sequence by the professionals who participate in the recruitment of patients will therefore be ensured. The intervention group will be taken directly to the registration page of "*e*-mpodera²" VCoP, where they will receive a personalized message to welcome them into the platform. To warrant patient participation and cooperation, this type of intervention cannot be blinded to patients. Data analysis will be blinded to the assignment of the intervention.

Data management

In order to maintain participant confidentiality all information will be stored with anonymized ID code numbers. The ID code numbers will be unrelated to participants' identifiers, except in a central file with the participants' contact details. All data will be stored on an electronic database management system located on a secure server with password-controlled access provided for research data collection. Databases will be designed to avoid downloading inappropriate values for every variable. Trial monitoring will be the responsibility of the core research team in charge of all quality control activities, assessing adherence to the trial protocol: timely work plan execution and comprehensiveness of data acquisition and data quality.

The Research Ethics Committees, the representatives of the Health Authority in matters of inspection and the personnel authorized by the Promoter, may only access to check personal data, clinical study procedures and compliance with the rules of good clinical practice (always maintaining the confidentiality of information).

Statistical analysis

Sociodemographic and clinical baseline variables for both groups will be analysed by descriptive methods (mean (SD), median (range), n (%)). The VCoP effect on the primary and secondary outcomes will be examined by means of multilevel linear regression, with the intervention, measurement time (0, 6, 12, 18 months) and their interaction as fixed effects (along with other potential covariates), random intercepts for patients and GP, and unstructured covariance to account for within-subject correlations. We will also analyse the three-way interaction intervention x time x centre, since usual care could vary between centres, leading to differential intervention effects. We expect to recruit a sufficient number of GPs to allow their inclusion in the model as a random intercept, but we will perform a sensitivity analysis as well excluding this component. Between-group differences at each time-point will be compared by means of Wald's χ^2 test.

We will perform the analyses on an intention-to-treat basis (a sensitivity analysis on the per-protocol population will be also performed). Multiple imputation will be used for missing data, if

applicable (Markov Chain Monte Carlo multivariate imputation algorithm, with 10 imputations per variable). Analyses will be carried out with the statistical software R 4.0.2 http://www.R-project.org/.

Cost-effectiveness analysis of the VCoP

We will carry out an economic evaluation, from baseline to 18-month follow-up, in which the costs and the results of the VCoP will be compared to the usual care following the recommendations of the guidelines for the management of patients with IHD (3–5), during the period of the clinical trial. The accepted analytical methods by the scientific community will be followed (50). The analysis will take both the perspective of the National Health System and of the social perspective. Therefore, direct healthcare costs and indirect costs will be included. The direct costs per patient will be calculated based on the use of healthcare resources, and the indirect costs will be estimated focusing on productivity losses due to IHD, applying the human capital approach. In addition to including the short-term costs (development and implementation of the VCoP), the costs observed during the follow-up will be included. We do not plan to consider opportunity costs in our cost-effectiveness analysis from the social perspective, as we understand that patients will use their free time on the VCoP and therefore they will not spend work or productive time not generating a cost for the system. The use of resources will be obtained from a patient self-reported questionnaire described in the outcome section. In addition, information about work absences related to the illness will be requested. The classic costs estimation approach will be followed multiplying the use of resources by their unit cost. The unit costs will be obtained from the eHealth cost database (*Oblikue Consulting*) and from public sources such as rates and PVP. The main outcome measure will be the incremental cost per gained QALY. The utilities for the estimation of the QALYs will be obtained through the EQ-5D-5L questionnaire (45) that will be completed by the patient at the beginning of the study and at each follow-up visit. Results of the cost-effectiveness analysis will be summarized as the incremental cost-effectiveness ratio (ICER). ICER is the ratio of the differences in costs to the differences in observed effects. Non-parametric

methods based on bootstrap simulations will be used to calculate confidence intervals in the ICER. The same nonparametric methods will be used to calculate the acceptability curve that represents the probability that each choice will be cost-effective for different cost-effectiveness thresholds. The willingness-to-pay threshold is defined at Euro 25,000/QALY on the basis of the values most recently reported in the Spanish literature (51). Finally, deterministic sensitivity analyses (one, two or several ways) will be carried out in order to assess the impact of the parameters on the cost-effectiveness results of the VCoP.

Patient and public involvement

This protocol was developed without patient or public involvement. A group of patients with IHD will actively participate in a content-design previous stage using a co-creation methodology with face-to-face sessions and virtual activities.

ETHICS AND DISSEMINATION

The study is registered on ClinicalTrials.gov. code NCT03959631 (https://clinicaltrials.gov/ct2/show/NCT03959631?recrs=b&type=Intr&cond=coronary+heart+disease&age=1&draw=2). Informed consent will be obtained from each participant before randomisation. The project received ethics approval from the local Committees at each participating Autonomous Community: Clinical Research Ethics Committee of Gregorio Marañón University Hospital in Madrid, Nuestra Señora de Candelaria University Hospital in Santa Cruz de Tenerife and from the coordinating centre IDIAP Jordi Gol in Barcelona (19/053-P). Patients will be personally informed by their physicians or nurses about the study and the possibility to participate during a programmed consultation. They will receive written information of the proposed research project, including information regarding the aims of the project, the duration of the participants' involvement, the expected benefits to the participant and the procedures involved in the participation. Recruiters will emphasize that enrolment in the study is voluntary and that participants can withdraw at any moment of the project and that any decision they take in this

respect will have no bearing on the medical care received. Once patients have signed the written informed consent, a researcher from the "*e*-mpodera²" team will contact them via phone and/ or mail to provide further information along with the necessary data (username and password) to login into the online platform. Additionally, recruiters will highlight that information generated by the study will be published, but no identification details will be divulged. Patients and health care providers will be informed of whom to contact in case of any query and research staff will be available to answer questions.

We will prepare presentations to disseminate the study findings to healthcare stakeholders and patients, and at relevant national and international conferences. We aim to publish the results of the trial in peer-reviewed journals.

TRIAL STATUS

The recruitment of patients in each region will start in September 2020. The estimated end date of the recruitment for this study is December 2020.

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CONTRIBUTORS

AIG wrote the initial draft of the protocol. CO is the guarantor of the trial. AIG, CO, LP, DK, VP and MB conceived the project. SG, AR and CV provided the methodological guidance. AT, VR, ATC, JMR, JCR, SD, LM, JGG, NVC, AR, JCdC, JMB, MET, MM, YdR and ABR are co-supervisors of this project, providing advice at all stages of the development of the protocol, and contributed to the revision of the manuscript. All authors read and approved the final manuscript.

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DISCLAIMER

The funder had no role in developing the protocol or obtaining the results for this review.

COMPETING INTERES

None declared

DATA SHARING

No additional data available

WORD COUNT

3,474

Table 1. Schedule of enrolment, interventions, and assessments (SPIRIT checklist)

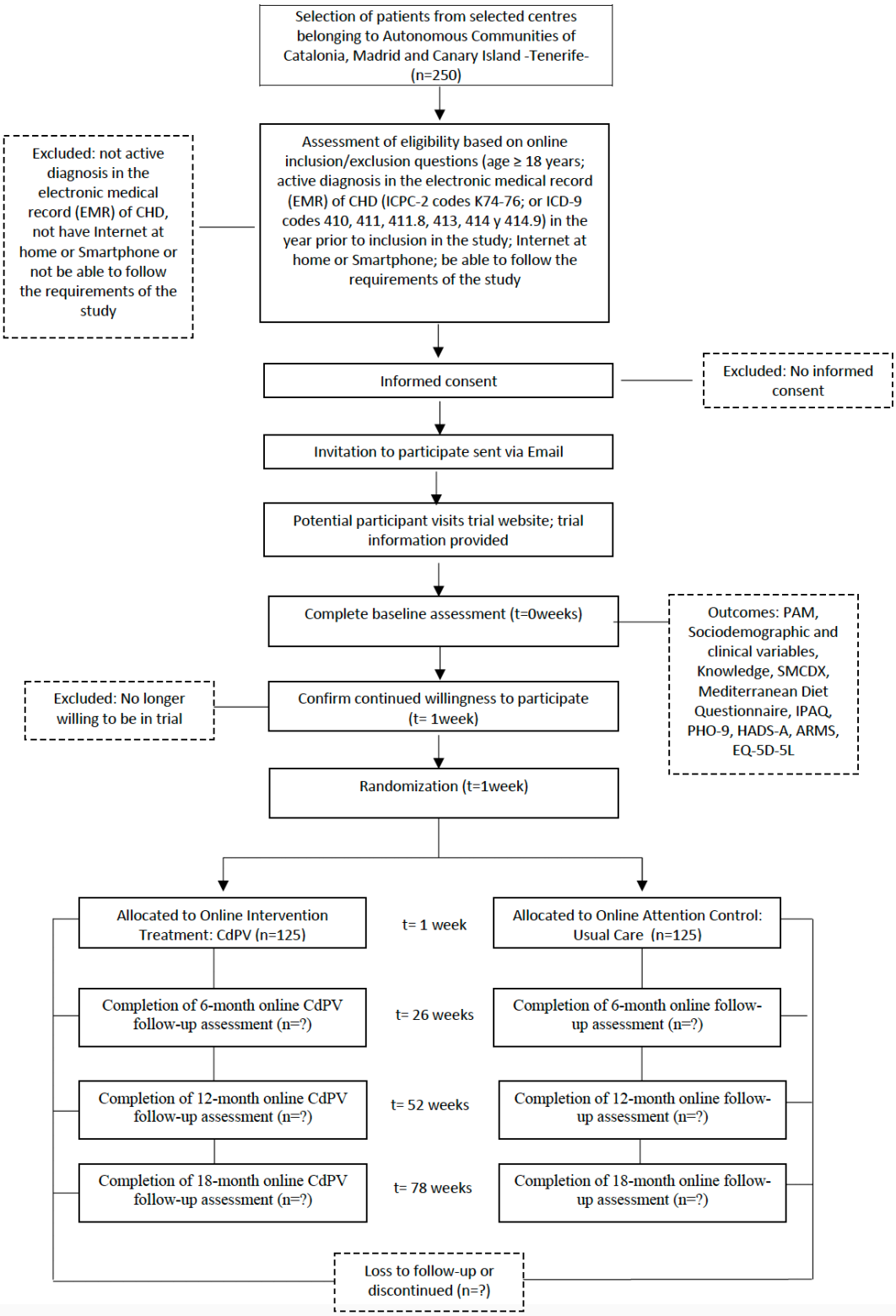
	STUDY PERIOD				
	Pre-allocation		Post-allocation		Close-out
TIMEPOINT	**Enrolment**	**Baseline**	**6 months**	**12 months**	**18 months**
Eligibility screen	X				
Informed consent	X				
INTERVENTIONS:					
VCoP					
Usual care					
ASSESSMENTS:					
PAM		X	X	X	X
Sociodemographic and clinical variables		X	X*	X*	X*
Knowledge		X	X	X	X
SMCDX		X	X	X	X
Mediterranean Diet Questionnaire		X	X	X	X
IPAQ		X	X	X	X
PHQ-9		X	X	X	X
HADS-A		X	X	X	X
ARMS-e		X	X	X	X
EQ-5D-5L		X	X	X	X
Use of resources			X	X	X
Use of VCoP					
Adverse events					

HADS = Hospital Anxiety and Depression Scale; IPAQ = International Physical Activity Questionnaire; ARMS-e = Adherence Refill and Medication Scale; PAM = Patient Activation

Measure; PHQ-9 = Patient Health Questionnaire; SMCDS = Self-efficacy Managing Chronic Disease Scale; VCoP = Virtual Community of Practice.
*Follow-up of just clinical variables

Figure 1. Flow of participants

Figure 1. Flow of participants



Additional file 1. SPIRIT checklist

Section / item	Item No	Description	Page
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	7
	2b	All items from the World Health Organization Trial Registration Data Set	7
Protocol version	3	Date and version identifier	7
Funding	4	Sources and types of financial, material, and other support	27
Roles and responsibilities	5a	Name, affiliations, and roles of protocol contributors	1-5, 26
	5b	Name and contact information for the trial sponsor	5
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	27
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	16-17
Introduction			
Background	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	9,10
	6b	Explanation for choice of comparators	9,10
Objectives	7	Specific objectives or hypotheses	10
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	10
Methods			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	10
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	10-11

Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	11-12
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	14
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	11-12
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	11-12
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	12-14
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see fig 1[f1])	15, 28-30
Sample size	14	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see fig 1[f1])	15, 28-30
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	15
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers) and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	16
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	16
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	16

Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts) and how	16
	17b	If blinded, circumstances under which unblinding is permissible and procedure for revealing a participant's allocated intervention during the trial	16
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	12-14
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	12-14
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	16
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	17,18
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	17,18
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	17,18
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	16-17
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	16-17
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	15
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	16-17
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	18,19
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to	18,19

		relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	18,19
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	18,19
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	18,19
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	27
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	16-17
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	18,19
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	18,19
	31b	Authorship eligibility guidelines and any intended use of professional writers	18,19
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	18,19
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	31-35
	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	NA

Additional file 2. Informed consent

HOJA DE INFORMACIÓN AL PACIENTE

FASE ENSAYO CLÍNICO

INTRODUCCIÓN

Estimado/a Sr/a:

Le comunicamos que se está desarrollando la puesta en marcha del ensayo clínico denominado **"Efectividad y coste-efectividad de una intervención virtual (Comunidad de Práctica) para la mejora del empoderamiento de pacientes con cardiopatía isquémica en atención primaria: ensayo controlado aleatorizado por conglomerados" (Cataluña: PI18/01404/, Madrid: PI18/01397, Canarias: PI18/01333).**

Este estudio ha sido aprobado por los Comités Éticos de los centros participantes de acuerdo con la legislación vigente, la Ley Orgánica 3/2018, de 5 de diciembre de Protección de Datos Personales y garantía de los derechos digitales, y a la aplicación del Reglamento (UE) 2016/679 del Parlamento europeo y del Consejo de 27 de abril de 2016 de Protección de Datos (RGPD) por el que se regula este tipo de estudios.

Nuestra intención es tan solo que usted reciba la información correcta y suficiente para que pueda evaluar y juzgar si quiere o no participar en este estudio. Para ello lea esta hoja informativa con atención y nosotros le aclararemos las dudas que le puedan surgir después de la explicación. Además, puede consultar con las personas que considere oportuno.

PARTICIPACIÓN VOLUNTARIA

Debe saber que su participación en este estudio es voluntaria y que puede decidir no participar o cambiar su decisión y retirar el consentimiento en cualquier momento, sin que por ello se altere la relación con su médico ni se produzca perjuicio alguno en su tratamiento.

¿Quiénes son los investigadores?

El equipo de investigación está formado por un equipo multidisciplinar (medicina, psicología, estadística y evaluación de servicios sanitarios, médicos de familia, enfermeras, cardiólogos) cuyos miembros pertenecen a las siguientes instituciones:

Fundación Avedis Donabedian, Gerencia Asistencial de Atención Primaria (GAAP) del Servicio Madrileño de Salud y Servicio de Evaluación del Servicio Canario de la Salud (SESCS).

Este proyecto ha surgido de una iniciativa colaborativa en el marco de la Red de Investigación en Servicios de Salud en Enfermedades Crónicas (REDISSEC).

DESCRIPCIÓN GENERAL DEL ESTUDIO

¿Por qué se hace este estudio?

Para evaluar la efectividad de una de una Comunidad de Práctica (CdP) virtual dirigida a pacientes con cardiopatía isquémica (CI) para mejorar su conocimiento, habilidades y autoconfianza para gestionar su propia salud y de la asistencia sanitaria que recibe.

¿Quién puede participar?

Si usted es mayor de 18 años, tiene cardiopatía isquémica, dispone de internet en su hogar y/o Smartphone.

Procedimiento del estudio:

Existirán dos grupos de estudio, Grupo de intervención (GI) y Grupo Control (GC), y a los pacientes se les asignará uno u otro al azar. En el caso de que usted quisiera participar en el estudio podría estar en cualquiera de los 2 grupos.

Si usted desea participar, ¿en qué consiste su participación?

La duración del estudio será de 18 meses. Al comienzo del estudio, a los 6, 12 y 18 meses, los participantes cumplimentarán unos cuestionarios online sobre aspectos relacionados con el nivel de activación de cada participante en las decisiones relacionadas con su salud (cuestionario PAM), el conocimiento de la enfermedad, la actitud hacia la enfermedad, la adherencia a la dieta mediterránea, la actividad física y algunos cuestionarios relacionados con variables psicológicas. Cumplimentar estos cuestionarios le llevará aproximadamente 30 minutos.

Si de forma aleatoria cae en el Grupo de intervención, se le ofrecerá participar durante 18 meses en una Comunidad de Práctica Virtual (CdPv) basada en una plataforma web 2.0. Se pondrá a disposición un enlace (vía email) para registrarse e iniciar la participación voluntaria.

Dentro de esta CdPv usted podrá disponer de elementos educativos, lúdicos y herramientas para facilitar el aprendizaje y la transferencia de conocimientos y de sus actitudes. Además, se trabajarán diversas temáticas relacionadas con: competencias en salud, técnicas de

autoeficacia, estilos de vida, aceptación de la enfermedad crónica y toma de decisiones compartida, dieta, planes de ejercicio, gestión del estrés, etc.

Si de forma aleatoria cae en el Grupo Control, usted seguirá los cuidados y atención propias de la práctica clínica habitual.

RIESGOS Y BENEFICIOS DE LA PARTICIPACIÓN EN ESTE ESTUDIO

No se prevé ningún tipo de riesgo físico ni psicológico que pueda ser consecuencia de la participación en este estudio.

El principal beneficio para los pacientes con CI será el contribuir a mejorar su conocimiento, habilidades y autoconfianza para la gestión de su propia salud y de la asistencia sanitaria.

CONFIDENCIALIDAD

El tratamiento, la comunicación y la cesión de los datos de carácter personal de todos los sujetos participantes se ajustará a lo dispuesto en la Ley Orgánica 3/2018, de 5 de diciembre de Protección de Datos Personales y garantía de los derechos digitales, y a la aplicación de del Reglamento (UE) 2016/679 del Parlamento europeo y del Consejo de 27 de abril de 2016 de Protección de Datos (RGPD), por lo que es importante que conozca la siguiente información:

- Además de los derechos que ya conoce (acceso, modificación, oposición y cancelación de datos) ahora también puede limitar el tratamiento de datos que sean incorrectos, solicitar una copia o que se trasladen a un tercero (portabilidad) los datos que usted ha facilitado para el estudio. Para ejercitar sus derechos, diríjase al investigador principal del estudio. Le recordamos que los datos no se pueden eliminar, aunque deje de participar en el estudio para garantizar la validez de la investigación y cumplir con los deberes legales y los requisitos de autorización de medicamentos. Así mismo tiene derecho a dirigirse a la Agencia de Protección de Datos si no quedara satisfecho/

- Tanto el Centro como el Promotor y el Investigador son responsables respectivamente del tratamiento de sus datos y se comprometen a cumplir con la normativa de protección de datos en vigor. Los datos recogidos para el estudio estarán identificados mediante un código, de manera que no se incluya información que pueda identificarle, y sólo su médico del estudio/colaboradores podrá relacionar dichos datos con usted y con su historia clínica. Por lo tanto, su identidad no será revelada a ninguna otra persona salvo a las autoridades sanitarias, cuando así lo requieran o en casos de urgencia médica. Los Comités de Ética de la Investigación, los representantes de la Autoridad Sanitaria en materia de inspección y el personal autorizado por el Promotor, únicamente podrán acceder para comprobar los datos

personales, los procedimientos del estudio clínico y el cumplimiento de las normas de buena práctica clínica (siempre manteniendo la confidencialidad de la información).

- El Investigador y el Promotor están obligados a conservar los datos recogidos para el estudio al menos hasta 25 años tras su finalización. Posteriormente, su información personal solo se conservará por el centro para el cuidado de su salud y por el promotor para otros fines de investigación científica si usted hubiera otorgado su consentimiento para ello, y si así lo permite la ley y requisitos éticos aplicables.

INFORMACIÓN ADICIONAL

Tal y como exige la ley, para participar deberá firmar y fechar el documento de consentimiento informado.

COORDINADORA DEL PROYECTO (CATALUÑA):
Dra. Carola Orrego, Fundación Avedis Donabedian
Contacto: corrego@fadq.org

INVESTIGADORA PRINCIPAL (MADRID):
Ana Isabel González González, Centro de Salud Vicente Muzas, Gerencia Asistencial de Atención Primaria. Servicio Madrileño de Salud
Contacto: aisabel.gonzalezg@salud.madrid.org

INVESTIGADORA PRINCIPAL (CANARIAS):
Lilisbeth Perestelo Pérez, Servicio de Evaluación del Servicio Canario de la Salud
Contacto: lperperr@gobiernodecanarias.org

CONSENTIMIENTO INFORMADO PARA PACIENTES

Yo (nombre y apellidos)

.....

He leído la hoja de información que se me ha entregado.
He podido hacer preguntas sobre el estudio.
He recibido suficiente información sobre el estudio.
He hablado con:

.....

Comprendo que mi participación es voluntaria.
Comprendo que puedo retirarme del estudio:

1º Cuando quiera
2º Sin tener que dar explicaciones.
3º Sin que esto repercuta en mis cuidados médicos.

- Presto libremente mi conformidad para participar en el estudio y doy mi consentimiento para el acceso y utilización de mis datos en las condiciones detalladas en la hoja de información.

Nombre del participante: **Nombre del investigador**:

Fecha: **Fecha**:

Firma: **Firma**: