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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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7 3 of patients with ischaemic heart disease: study protocol of a randomized controlled trial.
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2
3 132 **ABSTRACT**

4
5 133 **Introduction**

6
7 134 Virtual Communities of Practice (VCoP) offer ubiquitous access to information and exchange
8
9
10 135 possibilities for people in similar situations, which might be especially valuable for the self-
11
12 136 management of patients with chronic diseases. In view of the scarce evidence on the clinical and
13
14 137 economic impact of these interventions on chronic conditions, we aim to evaluate the
15
16 138 effectiveness and cost-effectiveness of a VCoP in the improvement of the activation and other
17
18 139 patient empowerment measures in patients with ischemic heart disease (IHD).

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20
21 140 **Methods and analysis**

22
23 141 A pragmatic randomised controlled trial will be performed in Catalonia, Madrid and Canary
24
25 142 Islands, Spain. Two hundred forty-six patients with a recent diagnosis of IHD attending the
26
27 143 participating centres will be selected and randomized to intervention or control group. The
28
29 144 intervention group will be offered participation for 12 months in a VCoP based on a gamified web
30
31 145 2.0 platform where there is interaction with other patients and a multidisciplinary professional
32
33 146 team. The control group will receive usual care. The primary outcome will be measured with the
34
35 147 Patient Activation Measure questionnaire at baseline, 6, 12 and 18 months. Secondary variables
36
37 148 will include: sociodemographic and clinical variables; knowledge test (Questionário de Fatores de
38
39 149 Risco Cardiovascular), attitudes (Self-efficacy Managing Chronic Disease Scale), adherence to
40
41 150 Mediterranean diet (Mediterranean Diet Questionnaire), level of physical activity (International
42
43 151 Physical Activity Questionnaire), depression (Patient Health Questionnaire), anxiety (Hospital
44
45 152 Anxiety Scale), medication adherence (Adherence to Refill and Medication Scale), quality of life
46
47 153 (EQ-5D-5L) and health resources use. Data will be collected from self-reported questionnaires and
48
49 154 electronic medical records.

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54 155 **Ethics and dissemination**

55
56 156 The trial was approved by Clinical Research Ethics Committee of Gregorio Marañón University
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58 157 Hospital in Madrid, Nuestra Señora de Candelaria University Hospital in Santa Cruz de Tenerife and
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3 158 IDIAP Jordi Gol in Barcelona. The results will be disseminated through workshops, policy briefs,
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5 159 peer-reviewed publications, local/international conferences.
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7 160 **Registration**
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9 161 ClinicalTrials.gov Identifier: NCT03959631
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3 162 **Strengths and limitations of this study**
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- 5 163 - We will experimentally test an innovative learning intervention based on a VCoP for patient
6
7 164 empowerment, for which the literature lacks experimental evaluations.
8
9 165 - VCoP can enhance communication between CoP members in different geographic locations
10
11 and even from different time zones.
12
13 166
14 167 - Participation rate can be low as similar experiences have shown; we will include the active role
15
16 168 of a community manager, weekly emails as reminders and a gamified competitive score
17
18 169 system to boost participation.
19
20 170 - Participation in the intervention group will require a minimum level of digital literacy so, the
21
22 171 results could not be generalized to all patients.
23
24 172 - Patients belonging to the control group and intervention group could receive different type of
25
26 173 self-management support depending on the centres where the care is provided.
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174 INTRODUCTION

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

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

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

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

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3 199 Interventions aimed at empowerment are intended to provide patients (and their informal
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5 200 caregivers, when appropriate) with the ability to participate in decisions related to their illness to
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7 201 the extent they wish, develop self-confidence, self-esteem and skills to face the physical,
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9 202 emotional and social impact of the disease in their daily lives (16,17).
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11 203 Virtual Communities of Practice (VCoP) offer ubiquitous access to information and exchange
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13 204 possibilities for people in similar situations, which is especially valuable in patients with chronic
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15 205 diseases. A CoP is a group of individuals who participate in a common activity and experience and
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17 206 create a shared identity and deepen their knowledge and experience in the area through a
18
19 207 continuous interaction that strengthens their relationships (18). In this context, a group of patients
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21 208 with the same illness such as IHD, could benefit from an intervention of these characteristics
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23 209 where they can share resources and information in addition to having the possibility of receiving
24
25 210 peer and professional support.
26
27 211 There is little research on the effect of VCoP in terms of their clinical and economic impact and on
28
29 212 the empowerment of patients with chronic diseases, especially with IHD (19,20). We propose to
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31 213 address this gap and, thus, present the protocol of a randomized controlled trial, which mainly
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33 214 aims to evaluate the effectiveness and cost-effectiveness of a VCoP to improve the activation and
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35 215 other measures related with patient empowerment in patients with IHD.
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217 **METHODS AND ANALYSIS**

218 **Study design**

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

221 **Study setting**

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

224 **Eligibility criteria**

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

226 *Inclusion criteria*

227 Age \geq 18 years; active diagnosis in the electronic medical record (EMR) of IHD (ICPC-2 codes K74-
228 76; or ICD-9 codes 410, 411, 411.8, 413, 414 y 414.9) in the year prior to inclusion in the study;
229 Internet at home or Smartphone; be able to follow the requirements of the study (e.g. digital
230 literacy); have signed the informed consent (Additional file 1).

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

232 *Exclusion criteria*

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

236 **Interventions**

237 *VCoP group*

238 "e-mpodera²" is a gamified VCoP on a web 2.0 platform based on the exchange of experiences and
239 knowledge through participatory learning (21). It will provide educational, playful elements and
240 tools that will facilitate the learning and transfer of knowledge and attitudes among patients with
241 IHD and with health care professionals. The structure and components will be designed according
242 to the needs and specifications of patients with IHD recruited in an earlier stage using a co-
243 creation methodology with face-to-face sessions and virtual activities (forums and interactions)
244 that incorporated a personalized itinerary – Patient Journey Map - (published elsewhere) and with
245 the use of various types of content including readings, resources, videos, games and virtual
246 sessions (21).

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

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2
3 251 patients and self-care of IHD will be progressively covered: health competence, self-efficacy and
4
5 252 activation improvement, behavioural changes, lifestyle / signs / symptoms monitoring, technical
6
7 253 skills, chronic disease acceptance and shared decision-making. Special emphasis will be given to
8
9 254 the changes recommended by European Guidelines (22) for self-management of IHD including
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11 255 monitoring changes in symptoms, stress management, mental health and adherence to
12
13 256 medication, diet, exercise plans, sodium cholesterol, and alcohol restriction and tobacco
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15 257 abstinence. The active role of a community manager, weekly emails as reminders and a gamified
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17 258 competitive score system will boost participation.
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21 259 *Usual care group*

22
23 260 Patients allocated to the control group will continue with their usual self- and professional care
24
25 261 according to the local guidelines (3–5).
26

27 262 **Outcomes measures**

28
29 263 *Primary outcome*

30
31 264 The primary outcome will be the patient activation level using the Patient Activation Measure
32
33 265 (PAM) questionnaire that assesses activation in patients with chronic diseases (12). The
34
35 266 questionnaire consists of 13 items that assesses knowledge, skills and confidence of people for
36
37 267 self-care, measured by a Likert 1-4 scale with a total score between 0 and 100 (100 identifies the
38
39 268 patients with the highest level of activation). The Spanish translated version has been validated in
40
41 269 patients with chronic diseases and has demonstrated a similar behaviour to the original
42
43 270 instrument with good validity and reliability properties (23). It has been used in previous studies
44
45 271 by this research team (24).
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49 272 *Secondary outcomes*

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51 273 For the effectiveness of the VCoP, we will record the following secondary measures:

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53 274 - Clinical variables such as body mass index, lipid profile (HDL-C, LDL-C), smoking status, number
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55 275 and frequency of angina episodes will be collected through researcher's developed online
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3 276 questionnaire that will be fulfilled by health care professionals combined with information
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5 277 from the EMR.
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7 278 - Knowledge about the disease will be assessed through a self-administered online
8
9 279 questionnaire based on the Questionário de Fatores de Risco Cardiovascular (Q-FARC) (25–27),
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11 280 previously translated from the English version and adapted to the Spanish population.
12
13 281 - Patients' attitudes to self-care will be evaluated using the self-administered Self-efficacy
14
15 282 Managing Chronic Disease Scale (SMCDS) (28), translated into Spanish (29) and used in
16
17 283 patients with heart failure (30).
18
19 284 - Adherence to Mediterranean diet will be assessed with the Mediterranean Diet questionnaire
20
21 285 (31), validated in the Spanish population in the PREDIMED study (32–34).
22
23 286 - Physical activity will be measured using the International Physical Activity Questionnaire
24
25 287 (IPAQ), translated and adapted to the Spanish language (35). Patients will be classified into
26
27 288 three categories (low, medium and high) according to the index of physical activity (product of
28
29 289 the intensity - in METS - by the frequency,) and the duration of the activity.
30
31 290 - Depressive disorders will be detected by the Patient Health Questionnaire-9 (PHQ-9) (36),
32
33 291 validated in Spanish with similar behaviour to the original and good acceptance (37).
34
35 292 - Anxiety will be assessed using the Hospital Anxiety and Depression Scale (HADS-A scale) (38), a
36
37 293 14-item questionnaire validated in PC in Spain (39,40), with special interest and usefulness in
38
39 294 the context of PC. It is a measure composed of two sub-scales (HAD-A: anxiety and HAD-D:
40
41 295 depression), of 7 items each that are scored from 0 to 3. The authors recommend a threshold
42
43 296 of 8 points to detect possible cases of anxiety. One of the main virtues of this tool is the
44
45 297 suppression of somatic symptoms. However, in patients with IHD it underestimates people
46
47 298 with depression (41), while the sub-scale HADS-A has good specificity and predictive value for
48
49 299 measuring anxiety in this PC (42).
50
51 300 - Adherence to medication will be assessed with the Adherence Refill and Medication Scale
52
53 301 (ARMS-e) (43), validated in Spain and used to measure adherence to medication in patients
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3 302 with chronic diseases. It consists of 12 questions and there is no cut-off point, the lower the
4
5 303 score, the better the adherence. To quantify adherence, a value of 1 to 4 (never, sometimes,
6
7 304 almost always or always) is assigned to each of the responses according to a Likert-type scale.
8
9
10 305 - Quality of life related to health (HRQoL) will be described and assessed with the EQ-5D-5L
11
12 306 index (44), a generic and standardized instrument developed by the EuroQoL Group, and
13
14 307 prepared in several languages, including Spanish, and used in PC (45). It relates the HRQoL
15
16 308 with the amount of life and offers a score for the gains in health, the Quality Adjusted Life Year
17
18 309 (QALY). The descriptive EQ-5D system comprises 5 dimensions (mobility, personal care, daily
19
20 310 activities, pain / discomfort and anxiety / depression).

21
22
23 311 *Explanatory and adjustment variables*

24
25 312 - Sociodemographic: age, sex, nationality, Autonomous Community of residence (Catalonia,
26
27 313 Madrid or Canary Islands), marital status (married/partner, single, separated/divorced,
28
29 314 widowed), living alone (yes/no), educational level (incomplete primary education, complete
30
31 315 primary education, secondary education, university or equivalent studies), income level and
32
33 316 employment status (46).
34
35
36 317 - Morbidity related: type of IHD (stable angina, unstable angina, MI), duration of IHD (months),
37
38 318 current diagnosis of heart failure in EMR (K86), left ventricular ejection fraction ($\leq 30\%$, 30-
39
40 319 35%, 35-45%, >45%), NYHA class (I-IV), number and description of chronic concomitant
41
42 320 diseases (47), pharmacological treatment (acetylsalicylic acid or
43
44 321 clopidogrel/ticagrelor/prasugrel, beta-blockers, statins, angiotensin-converting enzyme (ACE)
45
46 322 inhibitors, angiotensin II receptor blockers, other treatments), cardiac catheterization (yes/no)
47
48 323 and participation in a cardiac rehabilitation program before and during the study period
49
50 324 (yes/no).
51
52 325 - Use of health care resources: primary care (PC) visits, visits to the emergency department,
53
54 326 visits to specialists, number of hospitalizations, lengths of stay, prescribed medications, use of
55
56 327 diagnostic tests.
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3 328 - Loss of productivity: self-administered questionnaire about work absences related to the
4
5 329 illness.

6
7 330 - Use of the VCoP.

8
9 331 This information will be collected from a patient self-reported questionnaire that the research
10
11 332 team will elaborate combined with information from the EMR. VCoP use data will be collected
12
13 333 through the platform database.

14 334 **Adverse events**

15
16 335 All significant adverse events as well as unintended consequences for each group will be collected
17
18 336 and described by the site researcher, nominated for each PCP and hospital, and reported to the
19
20 337 core team. A special form to report trial-related adverse events has been developed and
21
22 338 distributed.

23 339 **Participant timeline**

24
25 340 Primary and secondary outcome measures will be collected before the start of the VCoP
26
27 341 intervention and at 6, 12 and 18 months. See Table 1.

28
29 342 [About here: Table 1 on Schedule of enrolment, interventions, and assessments (SPIRIT checklist)].

30 343 **Sample size**

31
32 344 The necessary number of patients to detect, by means of independent means test, an average
33
34 345 minimal important difference of 4 points (SD 10) in the PAM questionnaire (12,23) between the
35
36 346 intervention and usual care group, is 123 patients per arm. For this calculation we assume an
37
38 347 alpha error of 0.05, power of 80% and size is increased by the estimation of a 20% loss.

39 348 **Recruitment**

40
41 349 Patient recruitment will be organized on each Autonomous Community (Catalonia, Madrid or
42
43 350 Canary Islands). The recruitment will be supported by informative meetings with directors and
44
45 351 health care professionals (general practitioners, nurses, cardiologists) from the participating
46
47 352 centres. In these meetings, a 10-minute presentation describing the study aim, planned time
48
49 353 frame and tasks to be carried out by health care professionals, expected resources utilization and
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1
2
3 354 funding procedures will be detailed. Patients that fulfil inclusion criteria will be actively
4
5 355 encouraged by their health care professionals to participate by providing information about the
6
7 356 trial and collecting their informed consent and contact details (e.g. phone number / email). The
8
9 357 research team will invite potential participants via phone and mail to access the “e-mpodera²”
10
11 358 platform where they will be provided with a unique registration code (Figure 1). Patients will be
12
13
14 359 consecutively included in the study; recruitment will be continuous until the sample size is
15
16 360 reached.

17
18
19 361 [About here: Figure 1 on Flow of participants].

20 21 362 **Allocation and blinding**

22
23 363 Two hundred and forty-six patients will be randomly assigned to the intervention (VCoP) or control
24
25 364 group. The randomization will be central and automatically performed by the online “e-mpodera²”
26
27 365 platform and the assigned group will be communicated to the patient once he or she has entered
28
29 366 the platform and completed baseline assessment (Figure 1). Lack of knowledge of the
30
31 367 randomization sequence by the professionals who participate in the recruitment of patients will
32
33 368 therefore be ensured. The intervention group will be taken directly to the registration page of “e-
34
35 369 mpodera²” VCoP, where they will receive a personalized message to welcome them into the
36
37 370 platform. To warrant patient participation and cooperation, this type of intervention cannot be
38
39 371 blinded to patients. Data analysts will be blinded to the assignment of the intervention.

40 41 372 **Data management**

42
43 373 In order to maintain participant confidentiality all information will be stored with anonymized ID
44
45 374 code numbers. The ID code numbers will be unrelated to participants’ identifiers, except in a
46
47 375 central file with the participants’ contact details. All data will be stored on an electronic database
48
49 376 management system located on a secure server with password-controlled access provided for
50
51 377 research data collection. Databases will be designed to avoid downloading inappropriate values
52
53 378 for every variable. Trial monitoring will be the responsibility of the core research team in charge of
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2
3 379 all quality control activities, assessing adherence to the trial protocol: timely work plan execution
4
5 380 and comprehensiveness of data acquisition and data quality.
6

7 381 The Research Ethics Committees, the representatives of the Health Authority in matters of
8
9 382 inspection and the personnel authorized by the Promoter, may only access to check personal data,
10
11 383 clinical study procedures and compliance with the rules of good clinical practice (always
12
13 384 maintaining the confidentiality of information).
14
15

16 385 **Statistical analysis**

17
18 386 Sociodemographic and clinical baseline variables for both groups will be analysed by descriptive
19
20 387 methods (mean (SD), median (range), n (%)). The VCoP effect on the primary and secondary
21
22 388 outcomes will be examined by means of multilevel linear regression, with patients as a fixed factor
23
24 389 (level 1) and general practitioners as a random factor (level 2), adjusting for baseline scores of the
25
26 390 dependent variable. We will perform the analyses on an intention-to-treat basis (a sensitivity
27
28 391 analysis on the per-protocol population will be also performed). Multiple imputation will be used
29
30 392 for missing data, if applicable (Markov Chain Monte Carlo multivariate imputation algorithm, with
31
32 393 10 imputations per variable). Analyses will be carried out with the statistical software R Core Team
33
34 394 (2014) <http://www.R-project.org/> and PASW Statistics 18.
35
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38

39 395 *Cost-effectiveness analysis of the VCoP (5 months).*

40
41 396 We will carry out an economic evaluation in which the costs and the results of the VCoP will be
42
43 397 compared to the usual care following the recommendations of the guidelines for the management
44
45 398 of patients with IHD (3–5), during the period of the clinical trial. The accepted analytical methods
46
47 399 by the scientific community will be followed (48). The main outcome measure will be the
48
49 400 incremental cost per gained QALY. The utilities for the estimation of the QALYs will be obtained
50
51 401 through the EQ-5D-5L questionnaire (44) that will be completed by the patient at the beginning of
52
53 402 the study and at each follow-up visit.
54
55

56 403 The perspective of the economic analysis will be that of the National Health System, including only
57
58 404 direct health costs, and of the social perspective, including indirect costs associated with the loss
59
60

1
2
3 405 of productivity of patients. In addition to including the short-term costs (development and
4
5 406 implementation of the VCoP), the costs observed during the follow-up will be included. The unit
6
7 407 costs will be obtained from the eHealth cost database (*Oblikue Consulting*) and from public
8
9 408 sources such as rates and PVP. The utilization of resources will be obtained from a patient self-
10
11 409 reported questionnaire described in the outcome section. In addition, information about work
12
13 410 absences related to the illness will be requested. As a summary result measure, the incremental
14
15 411 cost-effectiveness ratio (ICER) that results from dividing the difference in costs between choices by
16
17 412 the difference in effectiveness will be used. Non-parametric methods based on bootstrap
18
19 413 simulations will be used to calculate confidence intervals in the ICER. The same nonparametric
20
21 414 methods will be used to calculate the acceptability curve that represents the probability that each
22
23 415 choice will be cost-effective for different cost-effectiveness thresholds. Finally, deterministic
24
25 416 sensitivity analyses (one, two or several ways) will be carried out in order to assess the impact of
26
27 417 the parameters on the cost-effectiveness results of the VCoP.

31 418 **Patient and public involvement**

32
33
34 419 This protocol was developed without patient or public involvement. A group of patients with IHD
35
36 420 will actively participate in a content-design previous stage using a co-creation methodology with
37
38 421 face-to-face sessions and virtual activities.

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42 423 **ETHICS AND DISSEMINATION**

43
44
45 424 The study is registered on ClinicalTrials.gov. code NCT03959631
46
47 425 (<https://clinicaltrials.gov/ct2/show/NCT03959631?recrs=b&type=Intr&cond=coronary+heart+dise>
48
49 426 [ase&age=1&draw=2](https://clinicaltrials.gov/ct2/show/NCT03959631?recrs=b&type=Intr&cond=coronary+heart+dise)). Informed consent will be obtained from each participant before
50
51 427 randomization. The project received ethics approval from the local Committees at each
52
53 428 participating Autonomous Community: Clinical Research Ethics Committee of Gregorio Marañón
54
55 429 University Hospital in Madrid, Nuestra Señora de Candelaria University Hospital in Santa Cruz de
56
57 430 Tenerife and from the coordinating centre IDIAP Jordi Gol in Barcelona (19/053-P). Patients will be
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3 431 personally informed by their physicians or nurses about the study and the possibility to participate
4
5 432 during a programmed consultation. They will receive written information of the proposed research
6
7 433 project, including information regarding the aims of the project, the duration of the participants'
8
9 434 involvement, the expected benefits to the participant and the procedures involved in the
10
11 435 participation. Recruiters will emphasize that enrolment in the study is voluntary and that
12
13 436 participants can withdraw at any moment of the project and that any decision they take in this
14
15 437 respect will have no bearing on the medical care received. Once patients have signed the written
16
17 438 informed consent, a researcher from the "e-mpodera" team will contact them via phone and/ or
18
19 439 mail to provide further information along with the necessary data (username and password) to
20
21 440 login into the online platform. Additionally, recruiters will highlight that information generated by
22
23 441 the study will be published, but no identification details will be divulged. Patients and health care
24
25 442 providers will be informed of whom to contact in case of any query and research staff will be
26
27 443 available to answer questions.

31
32 444 We will prepare presentations to disseminate the study findings to healthcare stakeholders and
33
34 445 patients, and at relevant national and international conferences. We aim to publish the results of
35
36 446 the trial in peer-reviewed journals.

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40 41 448 **TRIAL STATUS**

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43 449 The recruitment of patients in each region will start in March 2020. The estimated end date of the
44
45 450 recruitment for this study is August 2020.

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49 50 452 **REFERENCES**

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17 18 594 **CONTRIBUTORS**

19
20 595 AIG wrote the initial draft of the protocol. CO is the guarantor of the trial. AIG, CO, LP, DK, VP and

21
22 596 MB conceived the project. SG and AR provided the methodological guidance. AT, VR, ATC, JMR,

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24 597 JCR, SD, LM, JGG, NVC, AR, JCdC, MM, YdR, ET and ABR are co-supervisors of this project, providing

25
26 598 advice at all stages of the development of the protocol, and contributed to the revision of the

27
28 599 manuscript. All authors read and approved the final manuscript.
29

30 31 600 **FUNDINGS**

32
33 601 This study has been funded by Instituto de Salud Carlos III through the project “PI18/01404,

34
35 602 PI18/01397, PI18/01333”, Co-funded by European Regional Development Fund, (ERDF) “A way of

36
37 603 shaping Europe”
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39 40 604 **DISCLAIMER**

41
42 605 The funder had no role in developing the protocol or obtaining the results for this review.
43

44 45 606 **COMPETING INTERES**

46
47 607 None declared
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49 50 608 **DATA SHARING**

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52 609 No additional data available
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54 55 610 **PATIENT AND PUBLIC INVOLVEMENT**

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57 611 Not required
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59 60 612 **WORD COUNT**

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

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

Adverse events						
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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

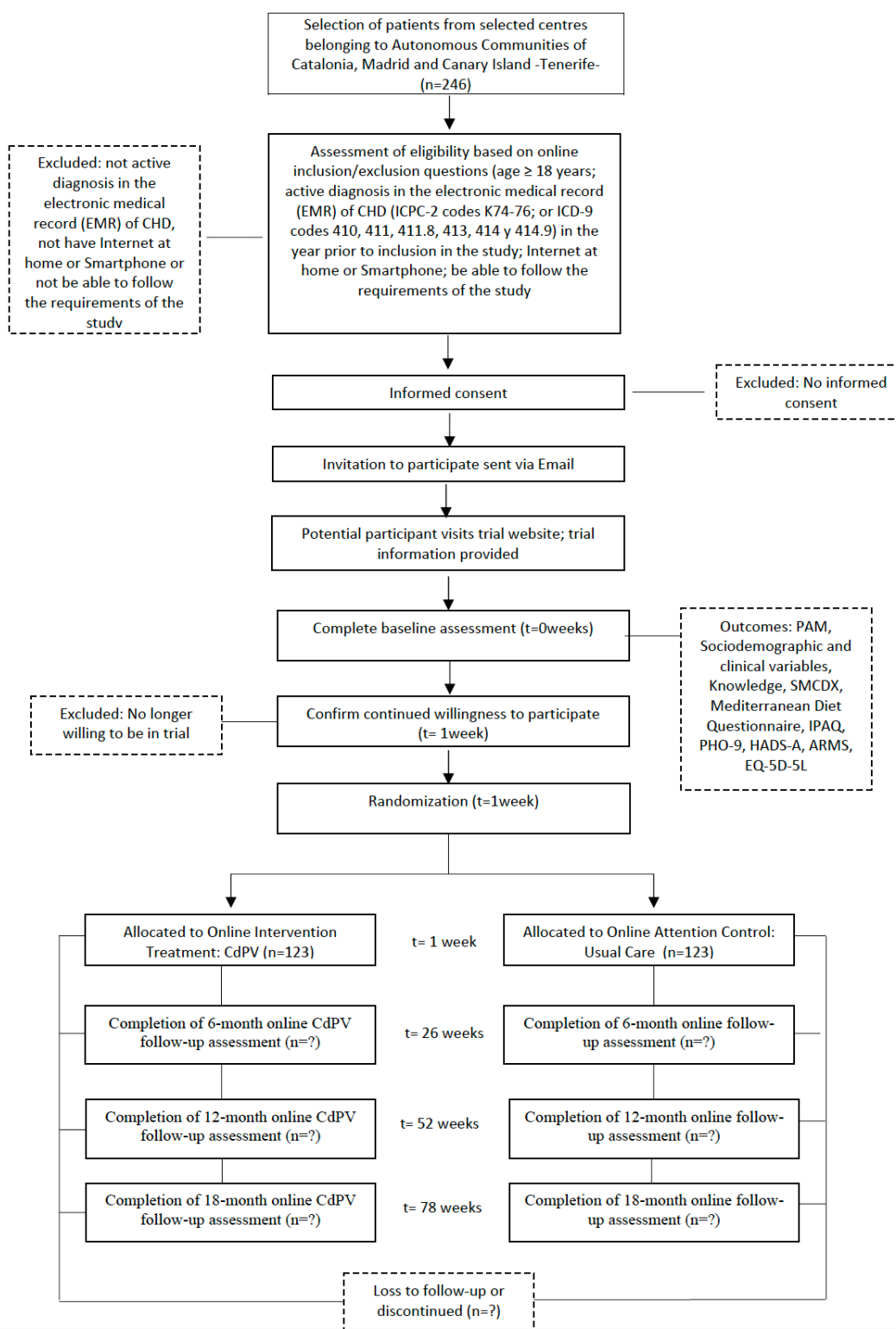
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3 **Figure 1. Flow of participants (54)**
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Figure 1. Flow of participants (49)



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

1
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3 autoeficacia, estilos de vida, aceptación de la enfermedad crónica y toma de decisiones
4 compartida, dieta, planes de ejercicio, gestión del estrés, etc.
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7 Si de forma aleatoria cae en el Grupo Control, usted seguirá los cuidados y atención propias
8 de la práctica clínica habitual.
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10 **RIESGOS Y BENEFICIOS DE LA PARTICIPACIÓN EN ESTE ESTUDIO**

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14 No se prevé ningún tipo de riesgo físico ni psicológico que pueda ser consecuencia de la
15 participación en este estudio.
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18 El principal beneficio para los pacientes con CI será el contribuir a mejorar su conocimiento,
19 habilidades y autoconfianza para la gestión de su propia salud y de la asistencia sanitaria.
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21 **CONFIDENCIALIDAD**

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23 El tratamiento, la comunicación y la cesión de los datos de carácter personal de todos los
24 sujetos participantes se ajustará a lo dispuesto en la Ley Orgánica 3/2018, de 5 de diciembre
25 de Protección de Datos Personales y garantía de los derechos digitales, y a la aplicación de
26 del Reglamento (UE) 2016/679 del Parlamento europeo y del Consejo de 27 de abril de 2016
27 de Protección de Datos (RGPD), por lo que es importante que conozca la siguiente
28 información:
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35 - Además de los derechos que ya conoce (acceso, modificación, oposición y cancelación de
36 datos) ahora también puede limitar el tratamiento de datos que sean incorrectos, solicitar
37 una copia o que se trasladen a un tercero (portabilidad) los datos que usted ha facilitado
38 para el estudio. Para ejercitar sus derechos, diríjase al investigador principal del estudio. Le
39 recordamos que los datos no se pueden eliminar, aunque deje de participar en el estudio
40 para garantizar la validez de la investigación y cumplir con los deberes legales y los
41 requisitos de autorización de medicamentos. Así mismo tiene derecho a dirigirse a la
42 Agencia de Protección de Datos si no quedara satisfecho/
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48 - Tanto el Centro como el Promotor y el Investigador son responsables respectivamente del
49 tratamiento de sus datos y se comprometen a cumplir con la normativa de protección de
50 datos en vigor. Los datos recogidos para el estudio estarán identificados mediante un
51 código, de manera que no se incluya información que pueda identificarle, y sólo su médico
52 del estudio/colaboradores podrá relacionar dichos datos con usted y con su historia clínica.
53 Por lo tanto, su identidad no será revelada a ninguna otra persona salvo a las autoridades
54 sanitarias, cuando así lo requieran o en casos de urgencia médica. Los Comités de Ética de
55 la Investigación, los representantes de la Autoridad Sanitaria en materia de inspección y el
56 personal autorizado por el Promotor, únicamente podrán acceder para comprobar los datos
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3 personales, los procedimientos del estudio clínico y el cumplimiento de las normas de
4 buena práctica clínica (siempre manteniendo la confidencialidad de la información).
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7 - El Investigador y el Promotor están obligados a conservar los datos recogidos para el
8 estudio al menos hasta 25 años tras su finalización. Posteriormente, su información
9 personal solo se conservará por el centro para el cuidado de su salud y por el promotor para
10 otros fines de investigación científica si usted hubiera otorgado su consentimiento para ello,
11 y si así lo permite la ley y requisitos éticos aplicables.
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15 **INFORMACIÓN ADICIONAL**

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18 Tal y como exige la ley, para participar deberá firmar y fechar el documento de
19 consentimiento informado.
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23 **COORDINADORA DEL PROYECTO (CATALUÑA):**

24 Dra. Carola Orrego, Fundación Avedis Donabedian

25 Contacto: corrego@fadq.org
26
27

28 **INVESTIGADORA PRINCIPAL (MADRID):**

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30 Atención Primaria. Servicio Madrileño de Salud

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33

34
35 **INVESTIGADORA PRINCIPAL (CANARIAS):**

36 Lilisbeth Perestelo Pérez, Servicio de Evaluación del Servicio Canario de la Salud

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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:

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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

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.

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2020-037374.R1
Article Type:	Protocol
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3 1 **TITLE**
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5 2 Effectiveness and cost-effectiveness of a virtual community of practice to improve the
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7 3 empowerment of patients with ischaemic heart disease: study protocol of a randomised
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9 4 controlled trial.
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1
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3 133 **ABSTRACT**

4
5 134 **Introduction**

6
7 135 Virtual Communities of Practice (VCoP) or knowledge-sharing virtual communities offer ubiquitous
8
9 136 access to information and exchange possibilities for people in similar situations, which might be
10
11 137 especially valuable for the self-management of patients with chronic diseases. In view of the
12
13 138 scarce evidence on the clinical and economic impact of these interventions on chronic conditions,
14
15 139 we aim to evaluate the effectiveness and cost-effectiveness of a VCoP in the improvement of the
16
17 140 activation and other patient empowerment measures in patients with ischemic heart disease
18
19 141 (IHD).

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23 142 **Methods and analysis**

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25 143 A pragmatic randomised controlled trial will be performed in Catalonia, Madrid and Canary
26
27 144 Islands, Spain. Two hundred fifty patients with a recent diagnosis of IHD attending the
28
29 145 participating centres will be selected and randomised to intervention or control group. The
30
31 146 intervention group will be offered participation for 12 months in a VCoP based on a gamified web
32
33 147 2.0 platform where there is interaction with other patients and a multidisciplinary professional
34
35 148 team. Intervention and control groups will receive usual care. The primary outcome will be
36
37 149 measured with the Patient Activation Measure questionnaire at baseline, 6, 12 and 18 months.
38
39 150 Secondary outcomes will include: clinical variables; knowledge (Questionnaire of Cardiovascular
40
41 151 Risk Factors), attitudes (Self-efficacy Managing Chronic Disease Scale), adherence to
42
43 152 Mediterranean diet (Mediterranean Diet Questionnaire), level of physical activity (International
44
45 153 Physical Activity Questionnaire), depression (Patient Health Questionnaire), anxiety (Hospital
46
47 154 Anxiety Scale-A), medication adherence (Adherence to Refill Medication Scale), quality of life (EQ-
48
49 155 5D-5L) and health resources use. Data will be collected from self-reported questionnaires and
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51 156 electronic medical records.

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57 157 **Ethics and dissemination**
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3 158 The trial was approved by Clinical Research Ethics Committee of Gregorio Marañón University
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5 159 Hospital in Madrid, Nuestra Señora de Candelaria University Hospital in Santa Cruz de Tenerife and
6
7 160 IDIAP Jordi Gol in Barcelona. The results will be disseminated through workshops, policy briefs,
8
9 161 peer-reviewed publications, local/international conferences.
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12 162 **Registration**
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14 163 ClinicalTrials.gov Identifier: NCT03959631
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3 164 **Strengths and limitations of this study**
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- 5 165 - We will experimentally test an innovative learning intervention based on a VCoP for patient
6
7 166 empowerment, for which the literature lacks experimental evaluations.
8
9 167 - VCoP can enhance communication between community members in different geographic
10
11 168 locations and even from different time zones.
12
13 169 - Participation rate can be low as similar experiences have shown; we will include the active role
14
15 170 of a community manager, weekly emails as reminders and a gamified competitive score
16
17 171 system to boost participation.
18
19 172 - Since all randomised patients will be required a minimum level of digital literacy so, the results
20
21 173 could not be generalized to all patients.
22
23 174 - Patients belonging to the control group and intervention group could receive different type of
24
25 175 self-management support depending on the centres where the care is provided.
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176 INTRODUCTION

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

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

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

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

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3 201 Interventions aimed at empowerment are intended to provide patients (and their informal
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5 202 caregivers, when appropriate) with the ability to participate in decisions related to their illness to
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7 203 the extent they wish, develop self-confidence, self-esteem and skills to face the physical,
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9 204 emotional and social impact of the disease in their daily lives (16,17).
10
11 205 Virtual Communities of Practice (VCoP) offer ubiquitous access to information and exchange
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13 206 possibilities for people in similar situations, which is especially valuable in patients with chronic
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15 207 diseases. A CoP is a group of individuals who participate in a common activity and experience and
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17 208 create a shared identity and deepen their knowledge and experience in the area through a
18
19 209 continuous interaction that strengthens their relationships (18). In this context, a group of patients
20
21 210 with the same illness such as IHD, could benefit from an intervention of these characteristics
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23 211 where they can share resources and information in addition to having the possibility of receiving
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25 212 peer and professional support.
26
27 213 There is little research on the effect of VCoP in terms of their clinical and economic impact and on
28
29 214 the empowerment of patients with chronic diseases, especially with IHD (19,20). We propose to
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31 215 address this gap and, thus, present the protocol of a randomised controlled trial, which mainly
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33 216 aims to evaluate the effectiveness and cost-effectiveness of a VCoP to improve the activation and
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35 217 other measures related with patient empowerment in patients with IHD.
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43 219 **METHODS AND ANALYSIS**44
45 220 This protocol has been prepared in accordance with the Standard Protocol Items:46
47 221 Recommendations for Interventional Trials (SPIRIT) checklist (Additional file 1) (21).48
49 222 [About here link to Additional file 1 on SPIRIT checklist].
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53 223 **Study design**54
55 224 We plan a pragmatic randomised controlled multicentre trial (*e-mpodera*²), with two parallel arms
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57 225 and 18-month follow-up.
5859 226 **Study setting**
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3 227 The setting of the intervention will be a virtual setting. Usual care will be provided at primary care
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5 228 practices (PCPs) and outpatient specialized clinics in Catalonia, Madrid and Canary Islands in Spain.
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8 229 **Eligibility criteria**

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10 230 Patients with a recent diagnosis of IHD will be screened for the following eligibility criteria:

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12 231 *Inclusion criteria*

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14 232 Age \geq 18 years; active diagnosis in the electronic medical record (EMR) of IHD (ICPC-2 codes K74-

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16 233 76; or ICD-9 codes 410, 411, 411.8, 413, 414 y 414.9) in the year prior to inclusion in the study;

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18 234 Internet at home or Smartphone; be able to follow the requirements of the study (e.g. digital

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20 235 literacy); have signed the informed consent (Additional file 2).

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22 236 [About here link to Additional file 2 on Informed consent].

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25 237 *Exclusion criteria*

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27 238 Institutionalized, terminal illness, physical or mental disability that limit the ability to answer the

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29 239 questionnaires or when telephone / email contact is not available in the PCPs/hospitals'

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31 240 databases.

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34 241 **Interventions**

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36 242 *VCoP group*

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38 243 "e-mpodera²" is a gamified VCoP on a web 2.0 platform based on the exchange of experiences and

39
40 244 knowledge through participatory learning (22). It will provide educational, playful elements and

41
42 245 tools that will facilitate the learning and transfer of knowledge and attitudes among patients with

43
44 246 IHD and with health care professionals. The structure and components will be designed according

45
46 247 to the needs and specifications of patients with IHD recruited in an earlier stage using a co-

47
48 248 creation methodology with face-to-face sessions and virtual activities (forums and interactions)

49
50 249 that incorporated a personalized itinerary – Patient Journey Map - (published elsewhere) and with

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52 250 the use of various types of content including readings, resources, videos, games and virtual

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54 251 sessions (22).
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3 252 Patients will have access to multidisciplinary professional support as needed and according to
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5 253 what was identified in the content-design stage (published elsewhere) will potentially include
6
7 254 general practitioners, cardiologists, psychologists, self-care and self-management specialists,
8
9 255 nutritionist and others as necessary. Various thematic areas related to the empowerment of
10
11 256 patients and self-care of IHD will be progressively covered: health competence, self-efficacy and
12
13 257 activation improvement, behavioural changes, lifestyle / signs / symptoms monitoring, technical
14
15 258 skills, chronic disease acceptance and shared decision-making. Special emphasis will be given to
16
17 259 the changes recommended by European Guidelines (23) for self-management of IHD including
18
19 260 monitoring changes in symptoms, stress management, mental health and adherence to
20
21 261 medication, diet, exercise plans, sodium cholesterol, and alcohol restriction and tobacco
22
23 262 abstinence. The active role of a community manager, weekly emails as reminders and a gamified
24
25 263 competitive score system will boost participation.
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29 264 *Usual care group*

30
31 265 Patients allocated to both the intervention and the control group will continue with their usual
32
33 266 self- and professional care according to the local guidelines (3–5).
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36 267 **Outcomes measures**

37 268 *Primary outcome*

38
39 269 The primary outcome will be the patient activation level using the Patient Activation Measure
40
41 270 (PAM) questionnaire that assesses activation in patients with chronic diseases (12). The
42
43 271 questionnaire consists of 13 items that assesses knowledge, skills and confidence of people for
44
45 272 self-care, measured by a Likert 1-4 scale with a total score between 0 and 100 (100 identifies the
46
47 273 patients with the highest level of activation). The Spanish translated version has been validated in
48
49 274 patients with chronic diseases and has demonstrated a similar behaviour to the original
50
51 275 instrument with good validity and reliability properties (24). It has been used in previous studies
52
53 276 by this research team (25).
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57 277 *Secondary outcomes*

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3 278 For the effectiveness of the VCoP, we will record the following secondary measures:
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5 279 - Clinical variables such as body mass index, lipid profile (HDL-C, LDL-C), smoking status, number
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7 280 and frequency of angina episodes will be collected through researcher developed online
8
9 281 questionnaire that will be fulfilled by health care professionals combined with information
10
11 282 from the EMR.
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14 283 - Knowledge about the disease will be assessed through a self-administered online
15
16 284 questionnaire based on the Questionnaire of Cardiovascular Risk Factors (Q-FARC) (26–28),
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18 285 previously translated from the English version and adapted to the Spanish population.
19
20 286 - Patients' attitudes to self-care will be evaluated using the self-administered Self-efficacy
21
22 287 Managing Chronic Disease Scale (SMCDS) (29), translated into Spanish (30) and used in
23
24 288 patients with heart failure (31).
25
26
27 289 - Adherence to Mediterranean diet will be assessed with the Mediterranean diet questionnaire
28
29 290 (32), validated in the Spanish population in the PREDIMED study (33–35).
30
31
32 291 - Physical activity will be measured using the International Physical Activity Questionnaire
33
34 292 (IPAQ), translated and adapted to the Spanish language (36). Patients will be classified into
35
36 293 three categories (low, medium and high) according to the index of physical activity (product of
37
38 294 the intensity - in METS - by the frequency,) and the duration of the activity.
39
40
41 295 - Depressive disorders will be detected by the Patient Health Questionnaire-9 (PHQ-9) (37),
42
43 296 validated in Spanish with similar behaviour to the original and good acceptance (38).
44
45
46 297 - Anxiety will be assessed using the Hospital Anxiety and Depression Scale (HADS-A scale) (39), a
47
48 298 14-item questionnaire validated in PC in Spain (40,41), with special interest and usefulness in
49
50 299 the context of PC. It is a measure composed of two sub-scales (HAD-A: anxiety and HAD-D:
51
52 300 depression), of 7 items each that are scored from 0 to 3. The authors recommend a threshold
53
54 301 of 8 points to detect possible cases of anxiety. One of the main virtues of this tool is the
55
56 302 suppression of somatic symptoms. However, in patients with IHD it underestimates people
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2
3 303 with depression (42), while the sub-scale HADS-A has good specificity and predictive value for
4
5 304 measuring anxiety in this PC (43).
6
7 305 - Adherence to medication will be assessed with the Adherence Refill and Medication Scale
8
9
10 306 (ARMS-e) (44), validated in Spain and used to measure adherence to medication in patients
11
12 307 with chronic diseases. It consists of 12 questions and there is no cut-off point, the lower the
13
14 308 score, the better the adherence. To quantify adherence, a value of 1 to 4 (never, sometimes,
15
16 309 almost always or always) is assigned to each of the responses according to a Likert-type scale.
17
18 310 - Quality of life related to health (HRQoL) will be described and assessed with the EQ-5D-5L
19
20 311 index (45,46), a generic and standardized instrument developed by the EuroQoL Group, and
21
22 312 prepared in several languages, including Spanish, and used in PC (47). It relates the HRQoL
23
24 313 with the amount of life and offers a score for the gains in health, the Quality Adjusted Life Year
25
26 314 (QALY). The descriptive EQ-5D-5L system comprises 5 dimensions (mobility, personal care,
27
28 315 daily activities, pain / discomfort and anxiety / depression).
29
30

31
32 316 *Explanatory and adjustment variables*
33

34 317 - Sociodemographic: age, sex, nationality, Autonomous Community of residence (Catalonia,
35
36 318 Madrid or Canary Islands), marital status (married/partner, single, separated/divorced,
37
38 319 widowed), living alone (yes/no), educational level (incomplete primary education, complete
39
40 320 primary education, secondary education, university or equivalent studies), income level and
41
42 321 employment status (48).
43
44 322 - Morbidity related: type of IHD (stable angina, unstable angina, MI), duration of IHD (months),
45
46 323 current diagnosis of heart failure in EMR (K86), left ventricular ejection fraction ($\leq 30\%$, 30-
47
48 324 35%, 35-45%, >45%), NYHA class (I-IV), number and description of chronic concomitant
49
50 325 diseases (49), pharmacological treatment (acetylsalicylic acid or
51
52 326 clopidogrel/ticagrelor/prasugrel, beta-blockers, statins, angiotensin-converting enzyme (ACE)
53
54 327 inhibitors, angiotensin II receptor blockers, other treatments), cardiac catheterization (yes/no)
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3 328 and participation in a cardiac rehabilitation program before and during the study period
4
5 329 (yes/no).
6
7 330 - Use of health care resources: primary care (PC) visits, visits to the emergency department,
8
9 331 visits to specialists, number of hospitalizations, lengths of stay, prescribed medications, use of
10
11 332 diagnostic tests.
12
13
14 333 - Loss of productivity: self-administered questionnaire about work absences related to the
15
16 334 illness.
17
18 335 - Use of the VCoP: number of logins into the platform.

19
20
21 336 This information will be collected online from a patient self-reported questionnaire that the
22
23 337 research team will elaborate combined with information from the EMR. VCoP use data will be
24
25 338 collected through the platform database.

26 27 339 **Adverse events**

28
29 340 All significant adverse events as well as unintended consequences for each group will be collected
30
31 341 and described by the site researcher, nominated for each PCP and hospital, and reported to the
32
33 342 core team. A special form to report trial-related adverse events has been developed and
34
35 343 distributed.

36 37 344 **Participant timeline**

38
39 345 Primary and secondary outcome measures will be collected before the start of the VCoP
40
41 346 intervention and at 6, 12 and 18 months. See Table 1.
42
43 347 [About here: Table 1 on Schedule of enrolment, interventions, and assessments (SPIRIT checklist)].

44 45 348 **Sample size**

46
47 349 Assuming an alpha error of 0.05 and power of 80%, the necessary number of patients to detect, by
48
49 350 means of independent two-sample t-test, an average minimal important difference of 4 points (SD
50
51 351 10) in the PAM questionnaire (12,24) between the intervention and usual care group, is 200
52
53 352 patients (100 per arm). Assuming a 20% loss to follow up, the required sample increases to 250
54
55 353 (125 per arm).
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1
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3 354 **Recruitment**
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5 355 Patient recruitment will be organized on each Autonomous Community (Catalonia, Madrid or
6
7 356 Canary Islands). The recruitment will be supported by informative meetings with directors and
8
9 357 health care professionals (general practitioners, nurses, cardiologists) from the participating
10
11 358 centres. In these meetings, a 10-minute presentation describing the study aim, planned time
12
13 359 frame and tasks to be carried out by health care professionals, expected resources utilization and
14
15 360 funding procedures will be detailed. Patients that fulfil inclusion criteria will be actively
16
17 361 encouraged by their health care professionals to participate by providing information about the
18
19 362 trial and collecting their informed consent and contact details (e.g. phone number / email). The
20
21 363 research team will invite potential participants via phone and mail to access the “e-mpodera²”
22
23 364 platform where they will be provided with a unique registration code (Figure 1). Patients will be
24
25 365 consecutively included in the study; recruitment will be continuous until the sample size is
26
27 366 reached.

28
29
30
31
32 367 [About here: Figure 1 on Flow of participants].
33

34 368 **Allocation and blinding**
35

36
37 369 Two hundred and fifty patients will be randomly assigned to the intervention (VCoP) or control
38
39 370 group. The randomisation, stratified by centre, will be central and automatically performed by the
40
41 371 online “e-mpodera²” platform and the assigned group will be communicated to the patient once
42
43 372 he or she has entered the platform and completed baseline assessment (Figure 1). Lack of
44
45 373 knowledge of the randomisation sequence by the professionals who participate in the recruitment
46
47 374 of patients will therefore be ensured. The intervention group will be taken directly to the
48
49 375 registration page of “e-mpodera²” VCoP, where they will receive a personalized message to
50
51 376 welcome them into the platform. To warrant patient participation and cooperation, this type of
52
53 377 intervention cannot be blinded to patients. Data analysis will be blinded to the assignment of the
54
55 378 intervention.
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59 379 **Data management**
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1
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3 380 In order to maintain participant confidentiality all information will be stored with anonymized ID
4
5 381 code numbers. The ID code numbers will be unrelated to participants' identifiers, except in a
6
7 382 central file with the participants' contact details. All data will be stored on an electronic database
8
9 383 management system located on a secure server with password-controlled access provided for
10
11 384 research data collection. Databases will be designed to avoid downloading inappropriate values
12
13
14 385 for every variable. Trial monitoring will be the responsibility of the core research team in charge of
15
16 386 all quality control activities, assessing adherence to the trial protocol: timely work plan execution
17
18 387 and comprehensiveness of data acquisition and data quality.

19
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21 388 The Research Ethics Committees, the representatives of the Health Authority in matters of
22
23 389 inspection and the personnel authorized by the Promoter, may only access to check personal data,
24
25 390 clinical study procedures and compliance with the rules of good clinical practice (always
26
27 391 maintaining the confidentiality of information).

392 **Statistical analysis**

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

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

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3 406 applicable (Markov Chain Monte Carlo multivariate imputation algorithm, with 10 imputations per
4
5 407 variable). Analyses will be carried out with the statistical software R 4.0.2 [http://www.R-](http://www.R-project.org/)
6
7 408 [project.org/](http://www.R-project.org/).

9 409 *Cost-effectiveness analysis of the VCoP (6, 12 and 18 months).*

11 410 We will carry out an economic evaluation in which the costs and the results of the VCoP will be
12
13 411 compared to the usual care following the recommendations of the guidelines for the management
14
15 412 of patients with IHD (3–5), during the period of the clinical trial. The accepted analytical methods
16
17 413 by the scientific community will be followed (50). The analysis will take both the perspective of the
18
19 414 National Health System and of the social perspective. Therefore, direct healthcare costs and
20
21 415 indirect costs will be included. The direct costs per patient will be calculated based on the use of
22
23 416 healthcare resources, and the indirect costs will be estimated focusing on productivity losses due
24
25 417 to IHD, applying the human capital approach. In addition to including the short-term costs
26
27 418 (development and implementation of the VCoP), the costs observed during the follow-up will be
28
29 419 included. The use of resources will be obtained from a patient self-reported questionnaire
30
31 420 described in the outcome section. In addition, information about work absences related to the
32
33 421 illness will be requested. The classic costs estimation approach will be followed multiplying the use
34
35 422 of resources by their unit cost. The unit costs will be obtained from the eHealth cost database
36
37 423 (*Oblikue Consulting*) and from public sources such as rates and PVP. The main outcome measure
38
39 424 will be the incremental cost per gained QALY. The utilities for the estimation of the QALYs will be
40
41 425 obtained through the EQ-5D-5L questionnaire (45) that will be completed by the patient at the
42
43 426 beginning of the study and at each follow-up visit. Results of the cost-effectiveness analysis will be
44
45 427 summarized as the incremental cost-effectiveness ratio (ICER). ICER is the ratio of the differences
46
47 428 in costs to the differences in observed effects. Non-parametric methods based on bootstrap
48
49 429 simulations will be used to calculate confidence intervals in the ICER. The same nonparametric
50
51 430 methods will be used to calculate the acceptability curve that represents the probability that each
52
53 431 choice will be cost-effective for different cost-effectiveness thresholds. The willingness-to-pay
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3 432 threshold is defined at Euro 25,000/QALY on the basis of the values most recently reported in the
4
5 433 Spanish literature (51). Finally, deterministic sensitivity analyses (one, two or several ways) will be
6
7 434 carried out in order to assess the impact of the parameters on the cost-effectiveness results of the
8
9 435 VCoP.

11 436 **Patient and public involvement**

12 437 This protocol was developed without patient or public involvement. A group of patients with IHD
13
14 438 will actively participate in a content-design previous stage using a co-creation methodology with
15
16 439 face-to-face sessions and virtual activities.
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23 441 **ETHICS AND DISSEMINATION**

24
25 442 The study is registered on ClinicalTrials.gov. code NCT03959631
26
27 443 (<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
28
29 444 randomisation. The project received ethics approval from the local Committees at each
30
31 445 participating Autonomous Community: Clinical Research Ethics Committee of Gregorio Marañón
32
33 446 University Hospital in Madrid, Nuestra Señora de Candelaria University Hospital in Santa Cruz de
34
35 447 Tenerife and from the coordinating centre IDIAP Jordi Gol in Barcelona (19/053-P). Patients will be
36
37 448 personally informed by their physicians or nurses about the study and the possibility to participate
38
39 449 during a programmed consultation. They will receive written information of the proposed research
40
41 450 project, including information regarding the aims of the project, the duration of the participants'
42
43 451 involvement, the expected benefits to the participant and the procedures involved in the
44
45 452 participation. Recruiters will emphasize that enrolment in the study is voluntary and that
46
47 453 participants can withdraw at any moment of the project and that any decision they take in this
48
49 454 respect will have no bearing on the medical care received. Once patients have signed the written
50
51 455 informed consent, a researcher from the "e-mpodera" team will contact them via phone and/ or
52
53 456 mail to provide further information along with the necessary data (username and password) to
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1
2
3 458 login into the online platform. Additionally, recruiters will highlight that information generated by
4
5 459 the study will be published, but no identification details will be divulged. Patients and health care
6
7 460 providers will be informed of whom to contact in case of any query and research staff will be
8
9 461 available to answer questions.

11 462 We will prepare presentations to disseminate the study findings to healthcare stakeholders and
12
13 463 patients, and at relevant national and international conferences. We aim to publish the results of
14
15 464 the trial in peer-reviewed journals.
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21 466 **TRIAL STATUS**

22
23 467 The recruitment of patients in each region will start in September 2020. The estimated end date of
24
25 468 the recruitment for this study is December 2020.
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5 615 **CONTRIBUTORS**
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7 616 AIG wrote the initial draft of the protocol. CO is the guarantor of the trial. AIG, CO, LP, DK, VP and
8

9 617 MB conceived the project. SG, AR and CV provided the methodological guidance. AT, VR, ATC,
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11 618 JMR, JCR, SD, LM, JGG, NVC, AR, JCdC, JMB, MET, MM, YdR and ABR are co-supervisors of this
12

13 619 project, providing advice at all stages of the development of the protocol, and contributed to the
14

15 620 revision of the manuscript. All authors read and approved the final manuscript.
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17

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19

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21

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23

24 624 shaping Europe"
25

26 625 **DISCLAIMER**
27

28 626 The funder had no role in developing the protocol or obtaining the results for this review.
29

30 627 **COMPETING INTERES**
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32 628 None declared
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34 629 **DATA SHARING**
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36 630 No additional data available
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38 631 **WORD COUNT**
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Table 1. Schedule of enrolment, interventions, and assessments (SPIRIT checklist)

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

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

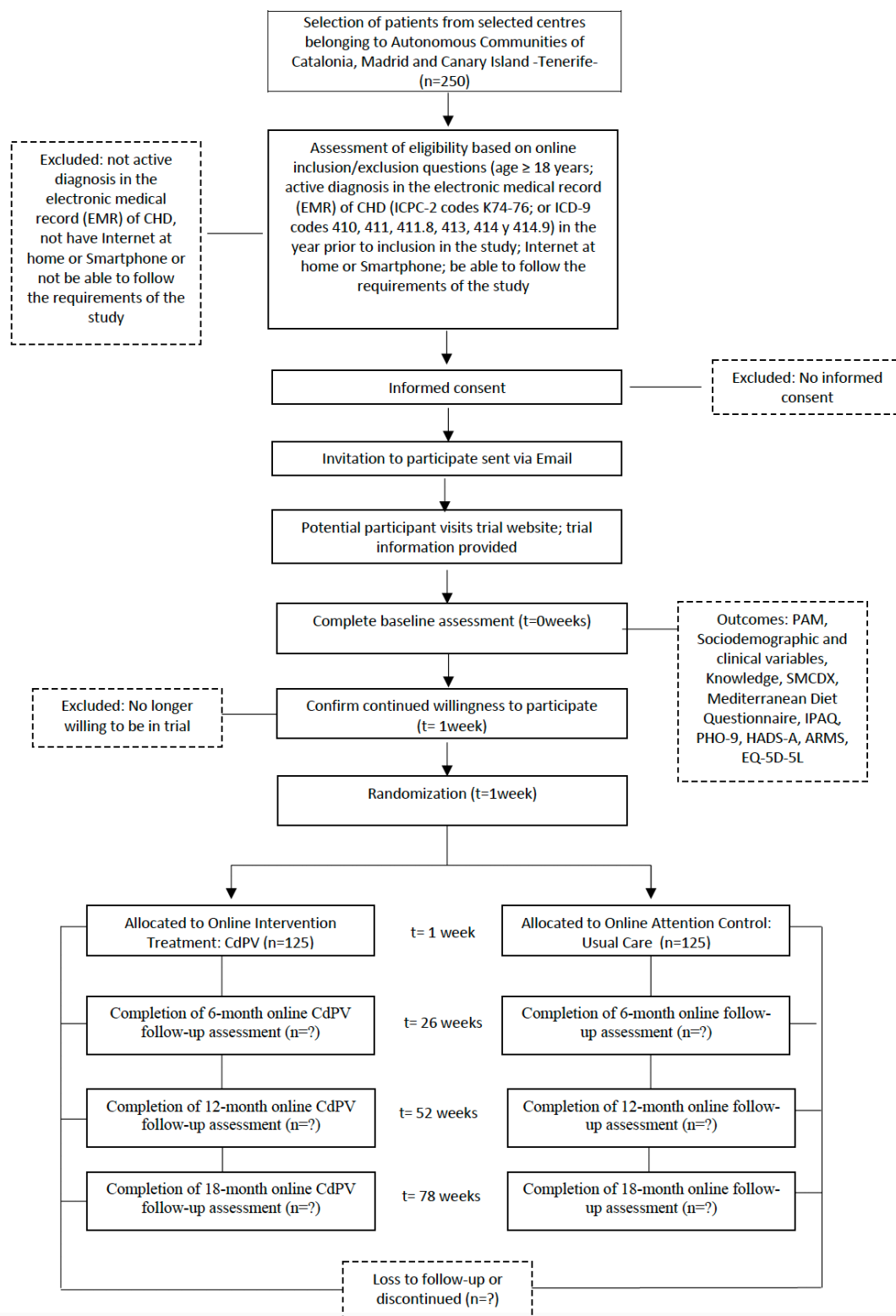
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3 Measure; PHQ-9 = Patient Health Questionnaire; SMCDS = Self-efficacy Managing Chronic Disease
4 Scale; VCoP = Virtual Community of Practice.
5 *Follow-up of just clinical variables
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For peer review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

Figure 1. Flow of participants

For peer review only

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

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3 autoeficacia, estilos de vida, aceptación de la enfermedad crónica y toma de decisiones
4 compartida, dieta, planes de ejercicio, gestión del estrés, etc.
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7 Si de forma aleatoria cae en el Grupo Control, usted seguirá los cuidados y atención propias
8 de la práctica clínica habitual.
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10 **RIESGOS Y BENEFICIOS DE LA PARTICIPACIÓN EN ESTE ESTUDIO**

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14 No se prevé ningún tipo de riesgo físico ni psicológico que pueda ser consecuencia de la
15 participación en este estudio.
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18 El principal beneficio para los pacientes con CI será el contribuir a mejorar su conocimiento,
19 habilidades y autoconfianza para la gestión de su propia salud y de la asistencia sanitaria.
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22 **CONFIDENCIALIDAD**

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25 El tratamiento, la comunicación y la cesión de los datos de carácter personal de todos los
26 sujetos participantes se ajustará a lo dispuesto en la Ley Orgánica 3/2018, de 5 de diciembre
27 de Protección de Datos Personales y garantía de los derechos digitales, y a la aplicación de
28 del Reglamento (UE) 2016/679 del Parlamento europeo y del Consejo de 27 de abril de 2016
29 de Protección de Datos (RGPD), por lo que es importante que conozca la siguiente
30 información:
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35 - Además de los derechos que ya conoce (acceso, modificación, oposición y cancelación de
36 datos) ahora también puede limitar el tratamiento de datos que sean incorrectos, solicitar
37 una copia o que se trasladen a un tercero (portabilidad) los datos que usted ha facilitado
38 para el estudio. Para ejercitar sus derechos, diríjase al investigador principal del estudio. Le
39 recordamos que los datos no se pueden eliminar, aunque deje de participar en el estudio
40 para garantizar la validez de la investigación y cumplir con los deberes legales y los
41 requisitos de autorización de medicamentos. Así mismo tiene derecho a dirigirse a la
42 Agencia de Protección de Datos si no quedara satisfecho/
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48 - Tanto el Centro como el Promotor y el Investigador son responsables respectivamente del
49 tratamiento de sus datos y se comprometen a cumplir con la normativa de protección de
50 datos en vigor. Los datos recogidos para el estudio estarán identificados mediante un
51 código, de manera que no se incluya información que pueda identificarle, y sólo su médico
52 del estudio/colaboradores podrá relacionar dichos datos con usted y con su historia clínica.
53 Por lo tanto, su identidad no será revelada a ninguna otra persona salvo a las autoridades
54 sanitarias, cuando así lo requieran o en casos de urgencia médica. Los Comités de Ética de
55 la Investigación, los representantes de la Autoridad Sanitaria en materia de inspección y el
56 personal autorizado por el Promotor, únicamente podrán acceder para comprobar los datos
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3 personales, los procedimientos del estudio clínico y el cumplimiento de las normas de
4 buena práctica clínica (siempre manteniendo la confidencialidad de la información).
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7 - El Investigador y el Promotor están obligados a conservar los datos recogidos para el
8 estudio al menos hasta 25 años tras su finalización. Posteriormente, su información
9 personal solo se conservará por el centro para el cuidado de su salud y por el promotor para
10 otros fines de investigación científica si usted hubiera otorgado su consentimiento para ello,
11 y si así lo permite la ley y requisitos éticos aplicables.
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15 **INFORMACIÓN ADICIONAL**

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18 Tal y como exige la ley, para participar deberá firmar y fechar el documento de
19 consentimiento informado.
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23 **COORDINADORA DEL PROYECTO (CATALUÑA):**

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CONSENTIMIENTO INFORMADO PARA PACIENTES

Yo (nombre y apellidos)

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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:

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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:

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For peer review only

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.

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2020-037374.R2
Article Type:	Protocol
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3 1 **TITLE**
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5 2 Effectiveness and cost-effectiveness of a virtual community of practice to improve the
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7 3 empowerment of patients with ischaemic heart disease: study protocol of a randomised
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9 4 controlled trial.
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3 133 **ABSTRACT**

4
5 134 **Introduction**

6
7 135 Virtual Communities of Practice (VCoP) or knowledge-sharing virtual communities offer ubiquitous
8
9 136 access to information and exchange possibilities for people in similar situations, which might be
10
11 137 especially valuable for the self-management of patients with chronic diseases. In view of the
12
13 138 scarce evidence on the clinical and economic impact of these interventions on chronic conditions,
14
15 139 we aim to evaluate the effectiveness and cost-effectiveness of a VCoP in the improvement of the
16
17 140 activation and other patient empowerment measures in patients with ischemic heart disease
18
19 141 (IHD).

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23 142 **Methods and analysis**

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25 143 A pragmatic randomised controlled trial will be performed in Catalonia, Madrid and Canary
26
27 144 Islands, Spain. Two hundred fifty patients with a recent diagnosis of IHD attending the
28
29 145 participating centres will be selected and randomised to intervention or control group. The
30
31 146 intervention group will be offered participation for 12 months in a VCoP based on a gamified web
32
33 147 2.0 platform where there is interaction with other patients and a multidisciplinary professional
34
35 148 team. Intervention and control groups will receive usual care. The primary outcome will be
36
37 149 measured with the Patient Activation Measure questionnaire at baseline, 6, 12 and 18 months.
38
39 150 Secondary outcomes will include: clinical variables; knowledge (Questionnaire of Cardiovascular
40
41 151 Risk Factors), attitudes (Self-efficacy Managing Chronic Disease Scale), adherence to
42
43 152 Mediterranean diet (Mediterranean Diet Questionnaire), level of physical activity (International
44
45 153 Physical Activity Questionnaire), depression (Patient Health Questionnaire), anxiety (Hospital
46
47 154 Anxiety Scale-A), medication adherence (Adherence to Refill Medication Scale), quality of life (EQ-
48
49 155 5D-5L) and health resources use. Data will be collected from self-reported questionnaires and
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51 156 electronic medical records.

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57 157 **Ethics and dissemination**
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3 158 The trial was approved by Clinical Research Ethics Committee of Gregorio Marañón University
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5 159 Hospital in Madrid, Nuestra Señora de Candelaria University Hospital in Santa Cruz de Tenerife and
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7 160 IDIAP Jordi Gol in Barcelona. The results will be disseminated through workshops, policy briefs,
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9 161 peer-reviewed publications, local/international conferences.
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12 162 **Registration**
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14 163 ClinicalTrials.gov Identifier: NCT03959631
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3 164 **Strengths and limitations of this study**
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- 5 165 - We will experimentally test an innovative learning intervention based on a VCoP for patient
6
7 166 empowerment, for which the literature lacks experimental evaluations.
8
9 167 - VCoP can enhance communication between community members in different geographic
10
11 168 locations and even from different time zones.
12
13 169 - Participation rate can be low as similar experiences have shown; we will include the active role
14
15 170 of a community manager, weekly emails as reminders and a gamified competitive score
16
17 171 system to boost participation.
18
19 172 - Since all randomised patients will be required a minimum level of digital literacy so, the results
20
21 173 could not be generalized to all patients.
22
23 174 - Patients belonging to the control group and intervention group could receive different type of
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25 175 self-management support depending on the centres where the care is provided.
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176 INTRODUCTION

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

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

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

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

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3 201 Interventions aimed at empowerment are intended to provide patients (and their informal
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5 202 caregivers, when appropriate) with the ability to participate in decisions related to their illness to
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7 203 the extent they wish, develop self-confidence, self-esteem and skills to face the physical,
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9 204 emotional and social impact of the disease in their daily lives (16,17).
10
11 205 Virtual Communities of Practice (VCoP) offer ubiquitous access to information and exchange
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13 206 possibilities for people in similar situations, which is especially valuable in patients with chronic
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15 207 diseases. A CoP is a group of individuals who participate in a common activity and experience and
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17 208 create a shared identity and deepen their knowledge and experience in the area through a
18
19 209 continuous interaction that strengthens their relationships (18). In this context, a group of patients
20
21 210 with the same illness such as IHD, could benefit from an intervention of these characteristics
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23 211 where they can share resources and information in addition to having the possibility of receiving
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25 212 peer and professional support.
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27 213 There is little research on the effect of VCoP in terms of their clinical and economic impact and on
28
29 214 the empowerment of patients with chronic diseases, especially with IHD (19,20). We propose to
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31 215 address this gap and, thus, present the protocol of a randomised controlled trial, which mainly
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33 216 aims to evaluate the effectiveness and cost-effectiveness of a VCoP to improve the activation and
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35 217 other measures related with patient empowerment in patients with IHD.
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42 219 **METHODS AND ANALYSIS**

43 220 This protocol has been prepared in accordance with the Standard Protocol Items:

44 221 Recommendations for Interventional Trials (SPIRIT) checklist (Additional file 1) (21).

45 222 [About here link to Additional file 1 on SPIRIT checklist].

46 223 **Study design**

47 224 We plan a pragmatic randomised controlled multicentre trial (*e-mpodera*²), with two parallel arms
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49 225 and 18-month follow-up.

50 226 **Study setting**

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3 227 The setting of the intervention will be a virtual setting. Usual care will be provided at primary care
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5 228 practices (PCPs) and outpatient specialized clinics in Catalonia, Madrid and Canary Islands in Spain.
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8 229 **Eligibility criteria**

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10 230 Patients with a recent diagnosis of IHD will be screened for the following eligibility criteria:

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12 231 *Inclusion criteria*

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14 232 Age \geq 18 years; active diagnosis in the electronic medical record (EMR) of IHD (ICPC-2 codes K74-

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16 233 76; or ICD-9 codes 410, 411, 411.8, 413, 414 y 414.9) in the year prior to inclusion in the study;

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18 234 Internet at home or Smartphone; be able to follow the requirements of the study (e.g. digital

19
20 235 literacy); have signed the informed consent (Additional file 2).

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22 236 [About here link to Additional file 2 on Informed consent].

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25 237 *Exclusion criteria*

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27 238 Institutionalized, terminal illness, physical or mental disability that limit the ability to answer the

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29 239 questionnaires or when telephone / email contact is not available in the PCPs/hospitals'

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31 240 databases.

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34 241 **Interventions**

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36 242 *VCoP group*

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38 243 "e-mpodera²" is a gamified VCoP on a web 2.0 platform based on the exchange of experiences and

39
40 244 knowledge through participatory learning (22). It will provide educational, playful elements and

41
42 245 tools that will facilitate the learning and transfer of knowledge and attitudes among patients with

43
44 246 IHD and with health care professionals. The structure and components will be designed according

45
46 247 to the needs and specifications of patients with IHD recruited in an earlier stage using a co-

47
48 248 creation methodology with face-to-face sessions and virtual activities (forums and interactions)

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50 249 that incorporated a personalized itinerary – Patient Journey Map - (published elsewhere) and with

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52 250 the use of various types of content including readings, resources, videos, games and virtual

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54 251 sessions (22).
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3 252 Patients will have access to multidisciplinary professional support as needed and according to
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5 253 what was identified in the content-design stage (published elsewhere) will potentially include
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7 254 general practitioners, cardiologists, psychologists, self-care and self-management specialists,
8
9 255 nutritionist and others as necessary. Various thematic areas related to the empowerment of
10
11 256 patients and self-care of IHD will be progressively covered: health competence, self-efficacy and
12
13 257 activation improvement, behavioural changes, lifestyle / signs / symptoms monitoring, technical
14
15 258 skills, chronic disease acceptance and shared decision-making. Special emphasis will be given to
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17 259 the changes recommended by European Guidelines (23) for self-management of IHD including
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19 260 monitoring changes in symptoms, stress management, mental health and adherence to
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21 261 medication, diet, exercise plans, sodium cholesterol, and alcohol restriction and tobacco
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23 262 abstinence. The active role of a community manager, weekly emails as reminders and a gamified
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25 263 competitive score system will boost participation.
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30 264 *Usual care group*

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32 265 Patients allocated to both the intervention and the control group will continue with their usual
33
34 266 self- and professional care according to the local guidelines (3–5).

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36 267 **Outcomes measures**

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38 268 *Primary outcome*

39
40 269 The primary outcome will be the patient activation level using the Patient Activation Measure
41
42 270 (PAM) questionnaire that assesses activation in patients with chronic diseases (12). The
43
44 271 questionnaire consists of 13 items that assesses knowledge, skills and confidence of people for
45
46 272 self-care, measured by a Likert 1-4 scale with a total score between 0 and 100 (100 identifies the
47
48 273 patients with the highest level of activation). The Spanish translated version has been validated in
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50 274 patients with chronic diseases and has demonstrated a similar behaviour to the original
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52 275 instrument with good validity and reliability properties (24). It has been used in previous studies
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54 276 by this research team (25).

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56 277 *Secondary outcomes*
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3 278 For the effectiveness of the VCoP, we will record the following secondary measures:
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5 279 - Clinical variables such as body mass index, lipid profile (HDL-C, LDL-C), smoking status, number
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7 280 and frequency of angina episodes will be collected through researcher developed online
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9 281 questionnaire that will be fulfilled by health care professionals combined with information
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11 282 from the EMR.
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14 283 - Knowledge about the disease will be assessed through a self-administered online
15
16 284 questionnaire based on the Questionnaire of Cardiovascular Risk Factors (Q-FARC) (26–28),
17
18 285 previously translated from the English version and adapted to the Spanish population.
19
20 286 - Patients' attitudes to self-care will be evaluated using the self-administered Self-efficacy
21
22 287 Managing Chronic Disease Scale (SMCDS) (29), translated into Spanish (30) and used in
23
24 288 patients with heart failure (31).
25
26
27 289 - Adherence to Mediterranean diet will be assessed with the Mediterranean diet questionnaire
28
29 290 (32), validated in the Spanish population in the PREDIMED study (33–35).
30
31
32 291 - Physical activity will be measured using the International Physical Activity Questionnaire
33
34 292 (IPAQ), translated and adapted to the Spanish language (36). Patients will be classified into
35
36 293 three categories (low, medium and high) according to the index of physical activity (product of
37
38 294 the intensity - in METS - by the frequency,) and the duration of the activity.
39
40
41 295 - Depressive disorders will be detected by the Patient Health Questionnaire-9 (PHQ-9) (37),
42
43 296 validated in Spanish with similar behaviour to the original and good acceptance (38).
44
45
46 297 - Anxiety will be assessed using the Hospital Anxiety and Depression Scale (HADS-A scale) (39), a
47
48 298 14-item questionnaire validated in PC in Spain (40,41), with special interest and usefulness in
49
50 299 the context of PC. It is a measure composed of two sub-scales (HAD-A: anxiety and HAD-D:
51
52 300 depression), of 7 items each that are scored from 0 to 3. The authors recommend a threshold
53
54 301 of 8 points to detect possible cases of anxiety. One of the main virtues of this tool is the
55
56 302 suppression of somatic symptoms. However, in patients with IHD it underestimates people
57
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1
2
3 303 with depression (42), while the sub-scale HADS-A has good specificity and predictive value for
4
5 304 measuring anxiety in this PC (43).
6
7 305 - Adherence to medication will be assessed with the Adherence Refill and Medication Scale
8
9 306 (ARMS-e) (44), validated in Spain and used to measure adherence to medication in patients
10
11 307 with chronic diseases. It consists of 12 questions and there is no cut-off point, the lower the
12
13 308 score, the better the adherence. To quantify adherence, a value of 1 to 4 (never, sometimes,
14
15 309 almost always or always) is assigned to each of the responses according to a Likert-type scale.
16
17
18 310 - Quality of life related to health (HRQoL) will be described and assessed with the EQ-5D-5L
19
20 311 index (45,46), a generic and standardized instrument developed by the EuroQoL Group, and
21
22 312 prepared in several languages, including Spanish, and used in PC (47). It relates the HRQoL
23
24 313 with the amount of life and offers a score for the gains in health, the Quality Adjusted Life Year
25
26 314 (QALY). The descriptive EQ-5D-5L system comprises 5 dimensions (mobility, personal care,
27
28 315 daily activities, pain / discomfort and anxiety / depression).
29
30

31
32 316 *Explanatory and adjustment variables*
33

34 317 - Sociodemographic: age, sex, nationality, Autonomous Community of residence (Catalonia,
35
36 318 Madrid or Canary Islands), marital status (married/partner, single, separated/divorced,
37
38 319 widowed), living alone (yes/no), educational level (incomplete primary education, complete
39
40 320 primary education, secondary education, university or equivalent studies), income level and
41
42 321 employment status (48).
43
44
45 322 - Morbidity related: type of IHD (stable angina, unstable angina, MI), duration of IHD (months),
46
47 323 current diagnosis of heart failure in EMR (K86), left ventricular ejection fraction ($\leq 30\%$, 30-
48
49 324 35%, 35-45%, >45%), NYHA class (I-IV), number and description of chronic concomitant
50
51 325 diseases (49), pharmacological treatment (acetylsalicylic acid or
52
53 326 clopidogrel/ticagrelor/prasugrel, beta-blockers, statins, angiotensin-converting enzyme (ACE)
54
55 327 inhibitors, angiotensin II receptor blockers, other treatments), cardiac catheterization (yes/no)
56
57
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59
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2
3 328 and participation in a cardiac rehabilitation program before and during the study period
4
5 329 (yes/no).
6
7 330 - Use of health care resources: primary care (PC) visits, visits to the emergency department,
8
9 331 visits to specialists, number of hospitalizations, lengths of stay, prescribed medications, use of
10
11 332 diagnostic tests.
12
13
14 333 - Loss of productivity: self-administered questionnaire about work absences related to the
15
16 334 illness.
17
18 335 - Use of the VCoP: number of logins into the platform and time spent using the platform.
19
20
21 336 This information will be collected online from a patient self-reported questionnaire that the
22
23 337 research team will elaborate combined with information from the EMR. VCoP use data will be
24
25 338 collected through the platform database.
26

27 339 **Adverse events**

28
29 340 All significant adverse events as well as unintended consequences for each group will be collected
30
31 341 and described by the site researcher, nominated for each PCP and hospital, and reported to the
32
33 342 core team. A special form to report trial-related adverse events has been developed and
34
35 343 distributed.
36
37
38

39 344 **Participant timeline**

40
41 345 Primary and secondary outcome measures will be collected before the start of the VCoP
42
43 346 intervention and at 6, 12 and 18 months. See Table 1.
44
45 347 [About here: Table 1 on Schedule of enrolment, interventions, and assessments (SPIRIT checklist)].
46
47

48 348 **Sample size**

49
50 349 Assuming an alpha error of 0.05 and power of 80%, the necessary number of patients to detect, by
51
52 350 means of independent two-sample t-test, an average minimal important difference of 4 points (SD
53
54 351 10) in the PAM questionnaire (12,24) between the intervention and usual care group, is 200
55
56 352 patients (100 per arm). Assuming a 20% loss to follow up, the required sample increases to 250
57
58 353 (125 per arm).
59
60

1
2
3 354 **Recruitment**
4

5 355 Patient recruitment will be organized on each Autonomous Community (Catalonia, Madrid or
6
7 356 Canary Islands). The recruitment will be supported by informative meetings with directors and
8
9 357 health care professionals (general practitioners, nurses, cardiologists) from the participating
10
11 358 centres. In these meetings, a 10-minute presentation describing the study aim, planned time
12
13 359 frame and tasks to be carried out by health care professionals, expected resources utilization and
14
15 360 funding procedures will be detailed. Patients that fulfil inclusion criteria will be actively
16
17 361 encouraged by their health care professionals to participate by providing information about the
18
19 362 trial and collecting their informed consent and contact details (e.g. phone number / email). The
20
21 363 research team will invite potential participants via phone and mail to access the “e-mpodera²”
22
23 364 platform where they will be provided with a unique registration code (Figure 1). Patients will be
24
25 365 consecutively included in the study; recruitment will be continuous until the sample size is
26
27 366 reached.

28
29
30
31
32 367 [About here: Figure 1 on Flow of participants].
33

34 368 **Allocation and blinding**
35

36
37 369 Two hundred and fifty patients will be randomly assigned to the intervention (VCoP) or control
38
39 370 group. The randomisation, stratified by centre, will be central and automatically performed by the
40
41 371 online “e-mpodera²” platform and the assigned group will be communicated to the patient once
42
43 372 he or she has entered the platform and completed baseline assessment (Figure 1). Lack of
44
45 373 knowledge of the randomisation sequence by the professionals who participate in the recruitment
46
47 374 of patients will therefore be ensured. The intervention group will be taken directly to the
48
49 375 registration page of “e-mpodera²” VCoP, where they will receive a personalized message to
50
51 376 welcome them into the platform. To warrant patient participation and cooperation, this type of
52
53 377 intervention cannot be blinded to patients. Data analysis will be blinded to the assignment of the
54
55 378 intervention.
56
57

58
59 379 **Data management**
60

1
2
3 380 In order to maintain participant confidentiality all information will be stored with anonymized ID
4
5 381 code numbers. The ID code numbers will be unrelated to participants' identifiers, except in a
6
7 382 central file with the participants' contact details. All data will be stored on an electronic database
8
9 383 management system located on a secure server with password-controlled access provided for
10
11 384 research data collection. Databases will be designed to avoid downloading inappropriate values
12
13
14 385 for every variable. Trial monitoring will be the responsibility of the core research team in charge of
15
16 386 all quality control activities, assessing adherence to the trial protocol: timely work plan execution
17
18 387 and comprehensiveness of data acquisition and data quality.

19
20
21 388 The Research Ethics Committees, the representatives of the Health Authority in matters of
22
23 389 inspection and the personnel authorized by the Promoter, may only access to check personal data,
24
25 390 clinical study procedures and compliance with the rules of good clinical practice (always
26
27 391 maintaining the confidentiality of information).

392 **Statistical analysis**

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

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

1
2
3 406 applicable (Markov Chain Monte Carlo multivariate imputation algorithm, with 10 imputations per
4
5 407 variable). Analyses will be carried out with the statistical software R 4.0.2 [http://www.R-](http://www.R-project.org/)
6
7 408 [project.org/](http://www.R-project.org/).

9
10 409 *Cost-effectiveness analysis of the VCoP*

11
12 410 We will carry out an economic evaluation, from baseline to 18-month follow-up, in which the costs
13
14 411 and the results of the VCoP will be compared to the usual care following the recommendations of
15
16 412 the guidelines for the management of patients with IHD (3–5), during the period of the clinical
17
18 413 trial. The accepted analytical methods by the scientific community will be followed (50). The
19
20 414 analysis will take both the perspective of the National Health System and of the social perspective.
21
22 415 Therefore, direct healthcare costs and indirect costs will be included. The direct costs per patient
23
24 416 will be calculated based on the use of healthcare resources, and the indirect costs will be
25
26 417 estimated focusing on productivity losses due to IHD, applying the human capital approach. In
27
28 418 addition to including the short-term costs (development and implementation of the VCoP), the
29
30 419 costs observed during the follow-up will be included. We do not plan to consider opportunity costs
31
32 420 in our cost-effectiveness analysis from the social perspective, as we understand that patients will
33
34 421 use their free time on the VCoP and therefore they will not spend work or productive time not
35
36 422 generating a cost for the system. The use of resources will be obtained from a patient self-
37
38 423 reported questionnaire described in the outcome section. In addition, information about work
39
40 424 absences related to the illness will be requested. The classic costs estimation approach will be
41
42 425 followed multiplying the use of resources by their unit cost. The unit costs will be obtained from
43
44 426 the eHealth cost database (*Oblikue Consulting*) and from public sources such as rates and PVP. The
45
46 427 main outcome measure will be the incremental cost per gained QALY. The utilities for the
47
48 428 estimation of the QALYs will be obtained through the EQ-5D-5L questionnaire (45) that will be
49
50 429 completed by the patient at the beginning of the study and at each follow-up visit. Results of the
51
52 430 cost-effectiveness analysis will be summarized as the incremental cost-effectiveness ratio (ICER).
53
54 431 ICER is the ratio of the differences in costs to the differences in observed effects. Non-parametric
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2
3 432 methods based on bootstrap simulations will be used to calculate confidence intervals in the ICER.
4
5 433 The same nonparametric methods will be used to calculate the acceptability curve that represents
6
7 434 the probability that each choice will be cost-effective for different cost-effectiveness thresholds.
8
9 435 The willingness-to-pay threshold is defined at Euro 25,000/QALY on the basis of the values most
10
11 436 recently reported in the Spanish literature (51). Finally, deterministic sensitivity analyses (one, two
12
13 437 or several ways) will be carried out in order to assess the impact of the parameters on the cost-
14
15 438 effectiveness results of the VCoP.

18 439 **Patient and public involvement**

20 440 This protocol was developed without patient or public involvement. A group of patients with IHD
21
22 441 will actively participate in a content-design previous stage using a co-creation methodology with
23
24 442 face-to-face sessions and virtual activities.
25
26 443

29 444 **ETHICS AND DISSEMINATION**

31 445 The study is registered on ClinicalTrials.gov. code NCT03959631
32
33 446 (<https://clinicaltrials.gov/ct2/show/NCT03959631?recrs=b&type=Intr&cond=coronary+heart+dise>
34
35 447 [ase&age=1&draw=2](https://clinicaltrials.gov/ct2/show/NCT03959631?recrs=b&type=Intr&cond=coronary+heart+dise&age=1&draw=2)). Informed consent will be obtained from each participant before
36
37 448 randomisation. The project received ethics approval from the local Committees at each
38
39 449 participating Autonomous Community: Clinical Research Ethics Committee of Gregorio Marañón
40
41 450 University Hospital in Madrid, Nuestra Señora de Candelaria University Hospital in Santa Cruz de
42
43 451 Tenerife and from the coordinating centre IDIAP Jordi Gol in Barcelona (19/053-P). Patients will be
44
45 452 personally informed by their physicians or nurses about the study and the possibility to participate
46
47 453 during a programmed consultation. They will receive written information of the proposed research
48
49 454 project, including information regarding the aims of the project, the duration of the participants'
50
51 455 involvement, the expected benefits to the participant and the procedures involved in the
52
53 456 participation. Recruiters will emphasize that enrolment in the study is voluntary and that
54
55 457 participants can withdraw at any moment of the project and that any decision they take in this
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1
2
3 458 respect will have no bearing on the medical care received. Once patients have signed the written
4
5 459 informed consent, a researcher from the “e-mpodera²” team will contact them via phone and/ or
6
7 460 mail to provide further information along with the necessary data (username and password) to
8
9 461 login into the online platform. Additionally, recruiters will highlight that information generated by
10
11 462 the study will be published, but no identification details will be divulged. Patients and health care
12
13 463 providers will be informed of whom to contact in case of any query and research staff will be
14
15 464 available to answer questions.
16
17

18 465 We will prepare presentations to disseminate the study findings to healthcare stakeholders and
19
20 466 patients, and at relevant national and international conferences. We aim to publish the results of
21
22 467 the trial in peer-reviewed journals.
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24
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26 468

27 469 **TRIAL STATUS**

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29
30 470 The recruitment of patients in each region will start in September 2020. The estimated end date of
31
32 471 the recruitment for this study is December 2020.
33

34 472

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12 618 **CONTRIBUTORS**

13
14 619 AIG wrote the initial draft of the protocol. CO is the guarantor of the trial. AIG, CO, LP, DK, VP and
15
16 620 MB conceived the project. SG, AR and CV provided the methodological guidance. AT, VR, ATC,
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18 621 JMR, JCR, SD, LM, JGG, NVC, AR, JCdC, JMB, MET, MM, YdR and ABR are co-supervisors of this
19
20 622 project, providing advice at all stages of the development of the protocol, and contributed to the
21
22 623 revision of the manuscript. All authors read and approved the final manuscript.
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24

25 624 **FUNDINGS**

26
27 625 This study has been funded by Instituto de Salud Carlos III through the project “PI18/01404,
28
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30
31 627 shaping Europe”
32
33

34 628 **DISCLAIMER**

35
36 629 The funder had no role in developing the protocol or obtaining the results for this review.
37

38 630 **COMPETING INTERES**

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40 631 None declared
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42 632 **DATA SHARING**

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44 633 No additional data available
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47 634 **WORD COUNT**

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

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

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

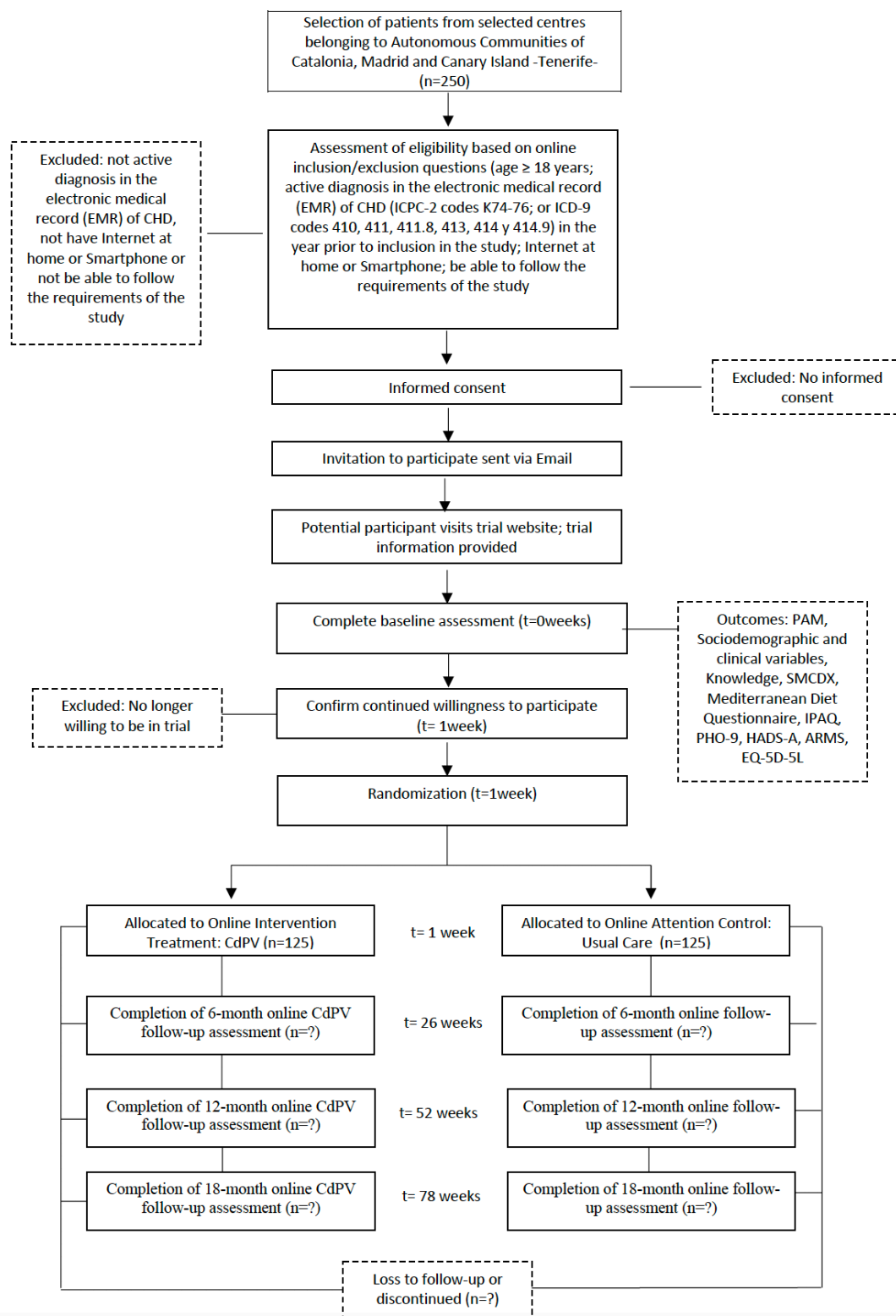
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3 Measure; PHQ-9 = Patient Health Questionnaire; SMCDS = Self-efficacy Managing Chronic Disease
4 Scale; VCoP = Virtual Community of Practice.
5 *Follow-up of just clinical variables
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For peer review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

Figure 1. Flow of participants

For peer review only

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

1
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3 autoeficacia, estilos de vida, aceptación de la enfermedad crónica y toma de decisiones
4 compartida, dieta, planes de ejercicio, gestión del estrés, etc.
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7 Si de forma aleatoria cae en el Grupo Control, usted seguirá los cuidados y atención propias
8 de la práctica clínica habitual.
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10 **RIESGOS Y BENEFICIOS DE LA PARTICIPACIÓN EN ESTE ESTUDIO**

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14 No se prevé ningún tipo de riesgo físico ni psicológico que pueda ser consecuencia de la
15 participación en este estudio.
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18 El principal beneficio para los pacientes con CI será el contribuir a mejorar su conocimiento,
19 habilidades y autoconfianza para la gestión de su propia salud y de la asistencia sanitaria.
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21 **CONFIDENCIALIDAD**

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23 El tratamiento, la comunicación y la cesión de los datos de carácter personal de todos los
24 sujetos participantes se ajustará a lo dispuesto en la Ley Orgánica 3/2018, de 5 de diciembre
25 de Protección de Datos Personales y garantía de los derechos digitales, y a la aplicación de
26 del Reglamento (UE) 2016/679 del Parlamento europeo y del Consejo de 27 de abril de 2016
27 de Protección de Datos (RGPD), por lo que es importante que conozca la siguiente
28 información:
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32 - Además de los derechos que ya conoce (acceso, modificación, oposición y cancelación de
33 datos) ahora también puede limitar el tratamiento de datos que sean incorrectos, solicitar
34 una copia o que se trasladen a un tercero (portabilidad) los datos que usted ha facilitado
35 para el estudio. Para ejercitar sus derechos, diríjase al investigador principal del estudio. Le
36 recordamos que los datos no se pueden eliminar, aunque deje de participar en el estudio
37 para garantizar la validez de la investigación y cumplir con los deberes legales y los
38 requisitos de autorización de medicamentos. Así mismo tiene derecho a dirigirse a la
39 Agencia de Protección de Datos si no quedara satisfecho/
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42 - Tanto el Centro como el Promotor y el Investigador son responsables respectivamente del
43 tratamiento de sus datos y se comprometen a cumplir con la normativa de protección de
44 datos en vigor. Los datos recogidos para el estudio estarán identificados mediante un
45 código, de manera que no se incluya información que pueda identificarle, y sólo su médico
46 del estudio/colaboradores podrá relacionar dichos datos con usted y con su historia clínica.
47 Por lo tanto, su identidad no será revelada a ninguna otra persona salvo a las autoridades
48 sanitarias, cuando así lo requieran o en casos de urgencia médica. Los Comités de Ética de
49 la Investigación, los representantes de la Autoridad Sanitaria en materia de inspección y el
50 personal autorizado por el Promotor, únicamente podrán acceder para comprobar los datos
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3 personales, los procedimientos del estudio clínico y el cumplimiento de las normas de
4 buena práctica clínica (siempre manteniendo la confidencialidad de la información).
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7 - El Investigador y el Promotor están obligados a conservar los datos recogidos para el
8 estudio al menos hasta 25 años tras su finalización. Posteriormente, su información
9 personal solo se conservará por el centro para el cuidado de su salud y por el promotor para
10 otros fines de investigación científica si usted hubiera otorgado su consentimiento para ello,
11 y si así lo permite la ley y requisitos éticos aplicables.
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15 **INFORMACIÓN ADICIONAL**

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17
18 Tal y como exige la ley, para participar deberá firmar y fechar el documento de
19 consentimiento informado.
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21

22
23 **COORDINADORA DEL PROYECTO (CATALUÑA):**

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27

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CONSENTIMIENTO INFORMADO PARA PACIENTES

Yo (nombre y apellidos)

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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:

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