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TITLE PAGE

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Implementation of a virtual community of practice to promote the empowerment of middle-aged people with multimorbidity: Study protocol of a randomized controlled trial.

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ABSTRACT

Introduction

Empowering people living with multimorbidity (multiple chronic conditions) to gain greater confidence in managing their health can enhance their quality of life. Education focused on self-management is a key tool for fostering patient empowerment and is mostly provided on an individual basis. Virtual Communities of Practice (VCoP) present a unique opportunity for online education in chronic condition self-management within a social context. This research aims to evaluate the effectiveness/cost-effectiveness of individualized, online self-management education compared to VCoP among middle-aged individuals living with multiple chronic conditions.

Methods and analysis

People aged 30-60, living with ≥2 chronic conditions, and receiving care in primary care centers and outpatient hospital-based clinics in Madrid and Canary Islands will enroll in an 18-month parallel-design, blinded (intervention assessment and data analysts), pragmatic (adhering to the intention-to-treat principle), individually randomized trial. The trial will compare two 12-month web-based educational offers of identical content; one delivered individually (control) and the other with online social interaction (VCoP, intervention). Using repeated measures mixed linear models, with the patient as random effect and allocation groups and time per group as fixed effects, we will estimate between-arm differences in the change in Patient Activation Measure (PAM) from baseline to 12 months (primary endpoint), including measurements at 6- and 18-months follow-up. Other outcomes will include measures of depression and anxiety, treatment burden, quality of life. In addition to a process evaluation of the VCoP, we will conduct an economic evaluation estimating the relative cost-effectiveness of the VCoP from the perspectives of both the National Health System and the Community.

Ethics and Dissemination

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

Trial registration: ClinicalTrials.gov. NCT06046326

STRENGTHS AND LIMITATIONS OF THIS STUDY

Strengths

- Pragmatic, multicenter design enhances the generalizability of the findings.
- Blinded assessment and data analysis reduce potential bias.
- Inclusion of both a control and intervention group allows for effective comparative analysis.
- Comprehensive outcome measures, including patient activation, mental health, and quality of life.
- Longitudinal follow-up (18 months) provides insights into the sustained effects of the interventions.

Limitations

- Limited to participants with internet access and digital literacy, which may affect the representativeness.
- Participation may be influenced by the willingness and ability of patients to engage in online communities.
- The study focuses on a specific age group (30-60 years), which may limit applicability to other age groups.
- The intervention's success relies heavily on active participation in the Virtual Community of Practice, which might vary among participants.
- The study is geographically limited to primary care centers and outpatient clinics in Madrid and the Canary Islands, which may affect generalizability.

INTRODUCTION

Multimorbidity is defined as the simultaneous presence of two or more chronic conditions in the same individual (1). Multimorbidity is becoming increasingly prevalent globally (2). While the prevalence of multimorbidity tends to rise with age (2), it is worth noting that more than 50% of individuals living with multiple chronic diseases are under the age of 65 (3-5).

Irrespective of age, individuals with multimorbidity tend to have a lower quality of life (6), use more healthcare services (7), and die younger (8) than people living with no or one chronic condition. However, how multimorbidity affects daily life may differ between middle-aged and older people.

It is in middle age when most chronic diseases first manifest. For middle-aged individuals with multimorbidity, the challenge lies in juggling the work of self-management with professional careers, childcare, eldercare, and leisure (9). Healthcare research has not adequately addressed the consequences of multimorbidity, in terms of an individual's capacity for self-care and the significant disruptions to family life, leisure, and community and professional commitments (10,11). Comprehensive, patient-centered strategies to address both medical and psychosocial aspects of care are urgently needed for middle-aged adults living with multimorbidity (12).

Empowerment is the process by which individuals gain control over managing the conditions of their daily life. Empowered individuals take actions to enhance their quality of life and possess the necessary knowledge, skills, attitudes, and self-perception to adapt their behavior and collaborate with others when required to achieve optimal well-being (13). There is a need for effective interventions that promote empowerment, self-confidence, self-esteem, and the ability to cope with the profound implications of multiple chronic diseases.

According to Wenger et al. (14), a Community of Practice (CoP) is a group of individuals engaged in a common activity who develop a shared identity, deepen their knowledge, and expand their experiences in a particular field through ongoing interactions that strengthen their relationships. A group of people sharing the common condition of multimorbidity may benefit from an intervention where they can interact, exchange knowledge, resources, information, and receive mutual and professional support.

Virtual Communities of Practice (VCoP) offer widespread access to information and opportunities for interaction among people facing similar situations, which is particularly valuable for individuals with chronic conditions. Key benefits encompass receiving and providing information, offering social support, boosting patient optimism, improving coping skills, brightening mood, reducing anxiety, and managing stress more effectively (15).

METHODS AND ANALYSIS

Aim

The main objective of this study is to assess the effectiveness and cost-effectiveness of two online self-management programs for chronic diseases. The first is delivered through a VCoP, fostering a community-based approach (intervention), while the second is provided on an individual basis (control). Other secondary objectives will be taken into account.

Trial design

We will conduct an 18-month, pragmatic, multicenter, parallel, randomized controlled trial. See Additional file 1 for SPIRIT checklist.

Study setting

Both groups will receive the intervention online as an add-on to their usual care at primary care practices and outpatient hospital-based clinics in Madrid and the Canary Islands, Spain.

Eligibility criteria and study population

Patients aged 30-60 and diagnosed with two or more chronic conditions will be identified by their healthcare providers (primary care and hospital physicians and nurses) and proposed to be screened by the research team for the following eligibility criteria:

Inclusion Criteria

1. Age 30 - 60 years.
2. Documentation of at least two chronic diseases in the electronic medical record (EMR) at the time of inclusion.
3. Access to the internet at home or via a smartphone.
4. Ability to meet the study requirements [e.g., digital literacy questionnaire (Additional file shows this in more details)].
5. Signed, written, informed consent.

Exclusion Criteria

1. Institutionalized individuals.
2. Receiving Palliative care.
3. Telephone/email contact information missing from clinic databases.

Recruitment and Implementation Strategies for Health Care Providers in Madrid and Canary Islands.

Recruitment Process

Health care providers (HCPs) from Madrid and the Canary Islands will be invited to participate in recruiting subjects for the study. To facilitate this process, the research team will conduct

informative sessions with HCPs, including nurses and physicians from outpatient clinics and primary care centers. These sessions will focus on detailing the project's objectives, outlining specific recruitment guidelines, and describing the responsibilities involved. Interested HCPs will then approach eligible patients, based on predefined inclusion criteria, to introduce them to the study's aims and requirements.

Patient Engagement and Information Dissemination

Patients expressing interest in the study will be contacted by a member of the researcher team. This step involves providing comprehensive information about the study, addressing any queries, and assessing the patients' familiarity with computer and internet usage. Following this, patients will gain access to a specialized web platform, designed exclusively for this project. This platform houses the informed consent document (see Additional file 3), which participants are required to understand and sign before proceeding. Subsequently, participants will complete baseline questionnaires, after which they will receive a one-year access to their assigned implementation strategy. For data management the patient ID will be anonymized. The study's flow-chart can be found in Figure 1.

Implementation Strategies Overview

To define the interventions, we used the taxonomy of self-management interventions for chronic diseases developed by Orrego et al. (16):

1) Intervention Group – "e-mpoderaT" Platform:
   - Platform Features: A gamified Virtual Community of Practice (VCoP), hosted on a Web 2.0 platform, will encourage the sharing of experiences and knowledge through collective learning (17). The platform will provide diverse educational and interactive

content, including forums, readings, resources, videos, games, and virtual sessions, all aimed at enhancing self-care and promoting knowledge exchange.

- Customization and Support: Tailored to address the unique needs of people with multimorbidity, this intervention will be co-created with patients and HCPs, leading to the development of a "Patient Journey Map". A healthcare professional experienced in facilitating patient groups will moderate the VCoP, ensuring active engagement, addressing queries, and fostering communication with a multidisciplinary team of experts, including general practitioners, cardiologists, psychologists, and nutritionists.
- Educational Focus: The content emphasizes patient empowerment dimensions like health competence, behavioral change, symptom monitoring, and shared decision-making, aligning with European guidelines for managing chronic diseases (17).

2) Control Group – Standard Care with Educational Access:

- Usual Care and Educational Resources: Participants in the control group will continue receiving standard care in line with local guidelines. Additionally, they will have access to a self-administered platform featuring the same educational content as the VCoP, minus the interactive and engagement components.

Table 1 summarizes the implementation strategy.

Description of materials and outcome measures

Primary outcome

The primary outcome will be the level of patient activation, assessed using the Patient Activation Measure (PAM) questionnaire (18). This questionnaire consists of 13 items that evaluate knowledge, skills, and confidence for self-care in patients with chronic conditions. Responses are measured on a Likert 1–4-point scale, resulting in a total score ranging from 0 to 100, with 100 indicating the highest level of patient activation. The Spanish-translated

version has been validated in patients with chronic diseases and exhibits good validity and reliability properties (19). The e-mpoderaT research team has previously employed this questionnaire in their studies (e-mpodera (20) and e-mpodera2 (21)).

Secondary outcomes

- *Depression*: The Patient Health Questionnaire-9 (PHQ-9) (22) will be used to detect depression, characterize its severity (23), and support follow-up (24). Validated in Spanish (25), it consists of 9 items that assess the presence of depressive symptoms in the last 2 weeks. Each item has a severity index: 0 = "never", 1 = "some days", 2 = "more than half the days" and 3 = "almost every day". A score between 0–4 indicates no depressive symptoms, 5–9 mild depressive symptoms, 10–14 moderate depressive symptoms, 15–19 moderately-severe depressive symptoms, and 20–27 severe depressive symptoms.

- *Anxiety*: The self-administered Hospital Anxiety and Depression Scale HADS-A subscale (26) is a 7-item questionnaire, validated in Spanish, and used in primary care (27- 29). Items are scored from 0 to 3, with a score of 8 indicating possible and >10 probable anxiety with good specificity and predictive value (30).

- *Treatment burden*: Based on the self-administered Treatment Burden Questionnaire - TBQ (31). A 10-item version was validated in primary care of the UK in patients with multimorbidity (32). It uses a Likert scale that ranges from 0 (not difficult / does not apply) to 4 (extremely difficult) to assess the burden related to taking medication, self-care, medical appointments, and the need for organization. We will translate and adapt the MTB Questionnaire using the forward and back-translation procedure.

- *Health-related quality of life (HRQoL)*: We will assess this construct using the self-administered EQ-5D-5L (33) validated in Spanish and used in primary care (34). It enables

the calculation of Quality-Adjusted Life Years (QALYs). The EQ-5D-5L descriptive system comprises five dimensions (mobility, personal care, daily activities, pain/discomfort, and anxiety/depression).

Explanatory and adjustment variables

- *Sociodemographic*: Age (years), gender, nationality, whether they live in Madrid or Canarias, marital status (married/partner, single, separated, divorced, widowed), number of living children, whether they have caregiving duties for parents (yes/no), educational level (incomplete primary studies, complete primary studies, secondary education, university studies or equivalent), and current occupation (i.e., unemployed, employed, self-employed, sick leave, another situation).

- *Morbidity*: Number and description of concomitant chronic diseases. This information will be collected by collaborating professionals coinciding with the baseline evaluation of each patient. An additional file of the O'Halloran list shows this in more detail (See Additional file 4) (35).

- *Treatment*: We will record the quantity and details of medications prescribed for long-term (i.e., at least three months), continuous use for each patient. This information will be meticulously collected by our team of collaborating HCPs at the time of each patient's baseline assessment, ensuring accurate and comprehensive medication data.

- *Use of resources*: primary care (PC) visits, visits to the emergency department, visits to specialists, number of hospitalizations, lengths of stay.

- *Use of VCoP*: VCoP use data will be collected through the platform database.

- *Unintended consequences* of the interventions will be monitored along the duration of the study (36).

See table 2 for more details.

Timeline

The primary outcome of our study (PAM), will be evaluated over a period of 12 months, starting from baseline. To ensure a thorough understanding of the PAM's progression, we will also conduct additional assessments at 6 and 18 months. Secondary outcome measures will be collected before the start of the VCoP intervention and at 6, 12 and 18 months. This information is shown with more details in Figure 2.

Data monitoring

The data will be monitored by the research team throughout the research process. Special attention will be paid to their quality and their correct collection. Primary analyzes will be conducted following completion of the 6-, 12-, and 18-month assessment questionnaires.

Randomization and blinding

STATA 17.0 software will generate a random sequence and will be used by an investigator to allocate participants after they have been enrolled and provided written consent. The intervention allocation will be blinded to participants, clinicians, and data analysts.

Statistical analysis

Sociodemographic and clinical baseline variables of both groups will be analyzed by descriptive methods according to the type of variable (mean [standard deviation (SD)], median [range], n [%]). The VCoP effect on the primary and secondary outcomes will be examined by means of repeated measures mixed linear models, with the intervention, time-point (0, 6, 12 and 18 months) and their interaction as fixed effects (along with other potential covariates), random intercepts for patients and clinicians, and unstructured covariance to account for

within-subject correlations. We will also analyze the three-way interaction intervention × time × center, since usual care could vary between centers, leading to differential intervention effects. We expect to recruit enough clinicians to allow their inclusion in the model as a random intercept, but we will perform a sensitivity analysis as well as excluding this component. Between-group differences at each time-point will be compared by means of Wald's $\chi 2$ test. We will perform the analyses on an intention-to-treat basis (a sensitivity analysis on the per-protocol population will also be performed). Multiple imputation will be used for missing data, if applicable (Markov Chain Monte Carlo multivariate imputation algorithm, with 10 imputations per variable). Analyses will be carried out with the statistical software R V.4.0.2 (http://www.R-project.org/).

Sample size

The necessary number of patients to detect, through independent means tests, a mean difference of 4 points (SD = 10) in the PAM questionnaire (18), between the intervention and control group, performing individual randomization, is 100 patients per arm. For this calculation, an alpha error of 0.05 and a power of 80% are assumed. This size is increased by the estimate of 20% loss, making a total of 240 patients.

Patient and public involvement

This protocol was developed without patient or public involvement. A group of middle-aged patients with multimorbidity will actively participate in a content-design previous stage using a co-creation methodology with virtual activities.

ETHICS AND DISSEMINATION

Informed consent (Additional file 3) will be obtained from each participant before randomization. The project has been approved by the local Ethics Committees of each

participating Autonomous Community: Clinical Research Ethics Committee of Gregorio Marañón University Hospital in Madrid (PI22/01124) and Nuestra Señora de Candelaria University Hospital in Santa Cruz de Tenerife (CHUNSC_2023_06). Patients will be personally informed by their physicians or nurses about the study and the possibility to participate during a programmed consultation. They will receive written information of the proposed research project, regarding its aims, the duration of their involvement, the expected benefits for them and the procedures involved in the participation. Recruiters will emphasize that enrollment in the study is voluntary, that participants can withdraw at any moment of the project, and that any decision they take in this respect will have no bearing on the medical care received. Once patients have signed the written informed consent, a researcher from the 'e-mpoderaT' team will contact them via phone and/or email to provide further information along with the necessary data (username and password) to login into the online platform. Additionally, recruiters will highlight that information generated by the study will be published, but no identification details will be divulged. Patients and healthcare professionals will be informed of whom to contact in case of any query, and research staff will be available to answer questions. We will prepare presentations to disseminate the study findings to healthcare stakeholders and patients, and at relevant national and international conferences. We aim to publish the results of the trial in peer-reviewed journals and try to grant public access to the full manuscripts.

DISCUSSION

The e-mpoderaT project will experimentally test two strategies: 1) an innovative learning intervention based on a VCoP for patient empowerment, for which the literature lacks experimental evaluations; and 2) an individual, self-administered education, without any kind

of interaction among participants. VCoPs can enhance communication between VCoP members in different geographic locations and even from different time zones. However, participation rate can be low, as similar experiences have shown (20); that is why we will include the active role of a community manager, who will engage participants, answer questions, and provide support and a multidisciplinary team of researchers will focus on designing content and developing strategies for the VCoP. The e-mpoderaT platform will automatically send weekly emails as reminders and a gamified competitive score system to boost participation. Participation in both groups will require a minimum level of digital literacy; therefore, the results would not be generalized to all patients. Patients belonging to the control group and intervention group will receive different types of self-management support depending on the healthcare centers where their usual care is provided.

This project aims to demonstrate that the strategy involving the VCoP, where participants can interact and provide mutual support, proves to be a better tool than the other strategy, just receiving online self-administrated educational content, to help middle-aged individuals with two or more chronic diseases because they would have greater activation and involvement in managing their health, thus becoming more empowered, with less depression and anxiety, and a reduced burden of treatment. They would improve their health-related quality of life and have a lower need for healthcare resources, such as hospital admissions and emergency room visits.

TRIAL STATUS

The recruitment of patients in each region will start in January-February 2024. The estimated end date of the recruitment for this study is June 2024. This information is shown in more detail in Figure 3.

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DECLARATIONS

Contributors

All the authors have contributed to the design of this study. All the authors will contribute to every step of the trial and will also contribute to the dissemination strategy.

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Consent for publication

Informed consent will be provided to all the participants (Additional file 3).

Availability of data and materials

To maintain participants confidentiality, all information will be stored with anonymized identification code (ID code) numbers. All data will be stored on an electronic database management system located on a secure server with password-controlled access provided for research data collection. The Research Ethics Committees, the representatives of the Health Authority in matters of inspection and the personnel authorized by the Promoter, may only access to check personal data, clinical study procedures and compliance with the rules of good clinical practice (always maintaining the confidentiality of information). Data will be available for any audit process.

Competing interests

The authors declare no conflict of interest.

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Word count

2724

Table 1. Implementation strategy.

INTERVENTION COMPONENTS	INTERVENTION GROUP "Virtual Community of Practice"	ACTIVE CONTROL "Self-administered education"
Provisioning and support methods	Provision of information Skills training Emotional support Proposal of objectives and action plans Training in self-monitoring of symptoms and monitoring of healthy behaviors Using reminders Social support by peers and professionals (key to the intervention)	Provision of information Using reminders
Type of encounters	Support sessions	Self-administered intervention
Support modality	Remote (web-based)	Remote (web-based)
Type of platform	Web platform compatible with mobile devices	Web platform compatible with mobile devices
Type of communication	Synchronous (webinar-type activities, virtual meetings) and asynchronous (web)	Asynchronous (web)
Recipients	In a group	Individual
Type of providers interacting with patients	Professionals in primary and specialized care medicine, nursing, psychology.	There is no interaction with patients.
Setting	Primary care patients	Primary care patients
Content topics (examples)	Healthy life habits Clinical management of pathologies (symptom management, pathology adherence) Emotional and stress management Social management (job compatibility, social roles)	Healthy life habits Clinical management of pathologies (symptom management, pathology adherence) Emotional and stress management Social management (job compatibility, social roles)
Outcomes measured	Activation, anxiety and depression, disease burden, quality of life, resource use	Activation, anxiety and depression, disease burden, quality of life, resource use
Type of patients	Middle-aged people with multimorbidity	Middle-aged people with multimorbidity
Content development	Co-designed. A multidisciplinary group of professionals prepares and reviews the contents. New contents according to the dynamics of participation and the needs of the group that participates in the community	Co-designed. A multidisciplinary group of professionals prepares and reviews the contents.

Source: Based on TIDieR guide (https://doi.org/10.1136/bmj.g1687) and Taxonomy of self-management interventions for chronic conditions (16).

Table 2. Trial outcomes

VARIABLES	NAME	TYPE OF VARIABLE	MEASURES
Primary	PAM (Patient Activation Measure)	Ordinal qualitative	Likert scale: 0-100, where 100 indicates highest level of activation
Secondary	PHQ-9 (Patient Health Questionnaire)	Ordinal qualitative	Likert scale: Depression intervals: 0-4, 5-9, 10-14, 15-19, 20-27
	HADS-A (Hospital Anxiety and Depression Scale: Subscale of Anxiety)	Ordinal qualitative	Likert scale: Scored each item 0-3. >8 indicates possible cases
	TBQ (Treatment Burden Questionnaire)	Ordinal qualitative	Likert scale: 0-20, where 20 indicates significant problem
	HRQoL (Health Related Quality of Life)	Ordinal qualitative	Likert scale: Never-very often
Sociodemographic	Age	Discrete quantitative	years
	Sex (Gender)	Categorical Qualitative	4 categories: 1-Male, 2- Female, 3-Other, 4- Refused to answer
	Nationality	Nominal	Open question
	Autonomous Community of residence	Categorical Qualitative	2 categories: 1-Madrid, 2-Canary Islands
	Marital status	Categorical Qualitative	5 categories: 1-Married/partner, 2-single, 3-separated, 4-divorced, 5-widowed
	Have children	Dichotomous qualitative	Yes/no
	Number of children	Discrete	Open question (number/units)
	Caring parents	Dichotomous qualitative	Yes/no

VARIABLES	NAME	TYPE OF VARIABLE	MEASURES
	Educational level	Categorical Qualitative	4 categories: 1-Incomplete primary studies, 2-complete primary studies, 3-secondary education, 4-university studies or equivalent
	Current occupation	Nominal	Open question
Multimorbidity	Number and description of concomitant chronic diseases	Discrete / Nominal	O'Halloran list
Treatment	Number and description of chronic treatments	Discrete / Nominal	Open question (number of treatments in electronic medical record)

Figure 1.- Implementation strategies flow-chart

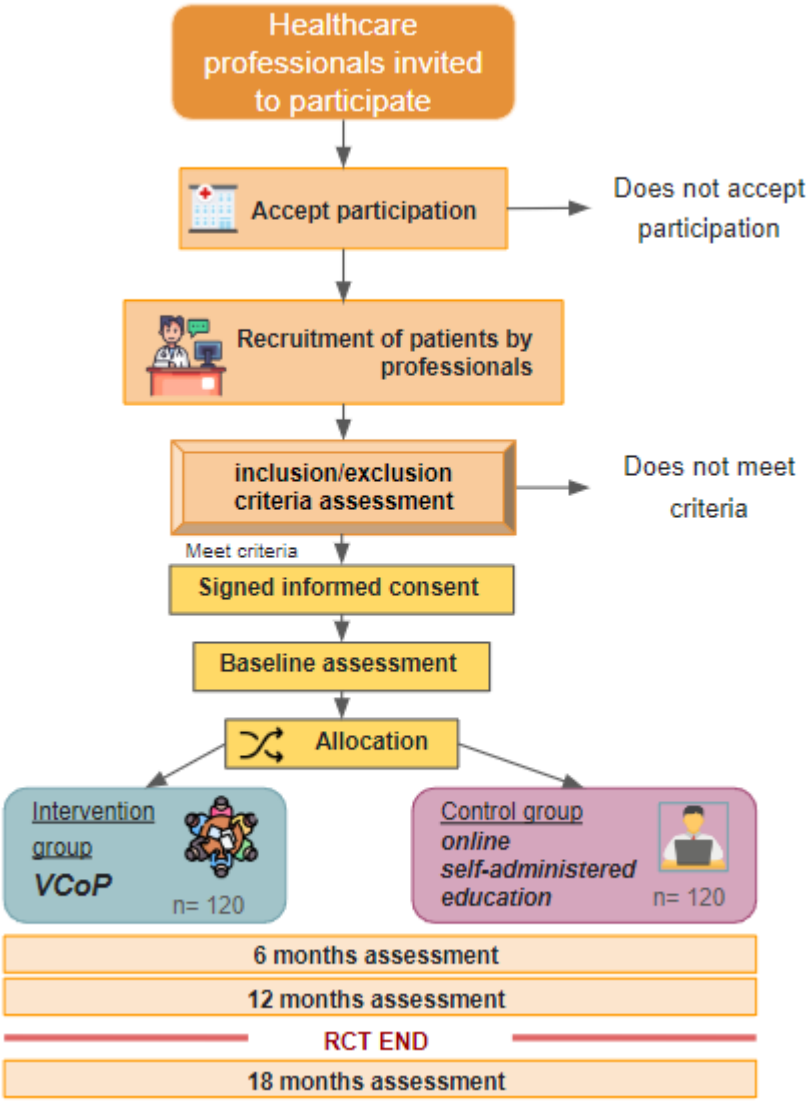


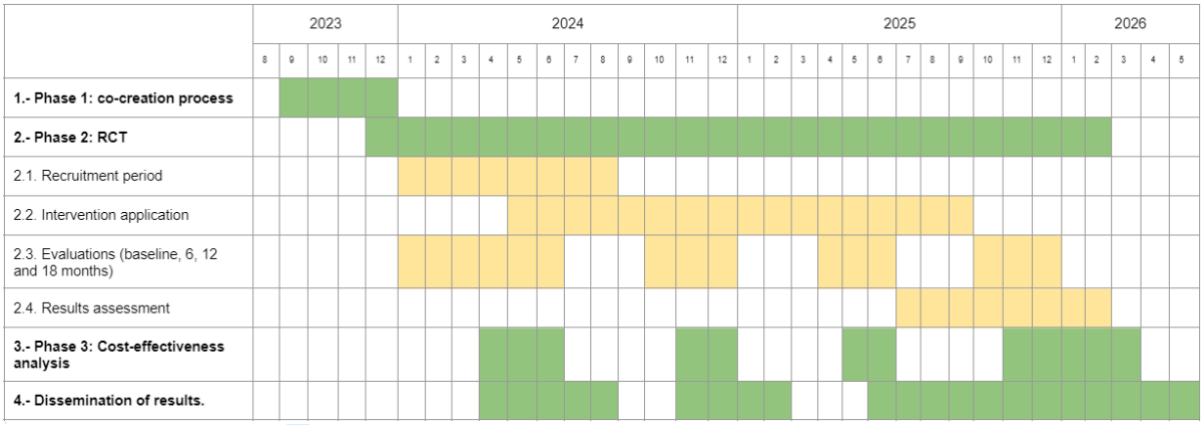
Figure 2. Schedule of enrolment, interventions, and assessments

	Study period					
		Preallocation		Postallocation		Close-out
	Phase 1	Enrolment	Baseline	6 months	12 months	18 months
Co-creation process	X					
Eligibility creen	X*	X				
Informed consent	X*	X				
Interventions						
VCoP						
Usual Care						
Assessments						
Sociodemographic variables			X			
Morbidity			X			
Treatment			X			
PAM			X	X	X	X
PHQ-9			X	X	X	X
HADS-A			X	X	X	X
TBQ			X	X	X	X
E5-5D-5L			X	X	X	X
Use of resources				X	X	X
Use of VCoP				X	X	
Unintended consequences				X	X	X

*The eligibility screen and informed consent of the co-creation phase are like the RCT phase.

HADS, Hospital Anxiety and Depression Scale; PAM, Patient Activation Measure; PHQ-9, Patient Health Questionnaire; TBQ, Treatment Burden Questionnaire; SPIRIT, Standard Protocol Items: Recommendations for Interventional Trials; VCoP, Virtual Community of Practice.

Figure 3. Project timeline



SPIRIT | CONSORT OUTCOMES
Reporting Guidelines for Trial Outcomes

Additional file 1 - SPIRIT-Outcomes 2022 Checklist (for combined completion of SPIRIT 2013 and SPIRIT-Outcomes 2022 items)

Section	Item	SPIRIT 2013 Item	SPIRIT-Outcomes 2022 item	Location Reported
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 ofintended registry	-	4
	2b	All items from the World HealthOrganization Trial RegistrationData Set	-	N/A
Protocol version	3	Date and version identifier	-	Left header
Funding	4	Sources and types of financial, material, and other support	-	4
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	-	1-2
	5b	Name and contact information for the trial sponsor	-	2
	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	-	N/A
	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 monitoringcommittee)	-	1-2
Introduction				
Background and rationale	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	-	5-6
	6b	Explanation for choice ofcomparators	-	5-6
Objectives	7	Specific objectives or hypotheses	-	6

Section	Item No.	SPIRIT 2013 Item	SPIRIT-Outcomes 2022 item	Location Reported
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)	-	6
Methods: Participants, interventions, and outcomes				
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	-	7
Eligibility criteria	10	Inclusion and exclusion criteria forparticipants. If applicable, eligibility criteria for study centres and individuals who will perform. the interventions (eg, surgeons, psychotherapists)	-	7
Interventions	11a	Interventions for each group withsufficient detail to allow replication, including how and when they will be administered. (for specific guidance see TIDieR checklist and guide)	-	9 (See Table 1)
	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)	-	N/A
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	-	N/A
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	-	9 (See Table 1)
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 theclinical relevance of chosen efficacy and harm outcomes is strongly recommended	-	10-12 (See Table 2)

Section	Item No.	SPIRIT 2013 Item	SPIRIT-Outcomes 2022 item	Location Reported
	12.1		Provide a rationale for the selection of the domain for the trial's primary outcome	10
	12.2		If the analysis metric for the primary outcome represents within-participant change, define, and justify the minimal important change in individuals	14
	12.3		If the outcome data collected are continuous but will be analyzed as categorical (method of aggregation), specify the cutoff values to be used	N/A
	12.4		If outcome assessments will be performed at several time points after randomization, state the time points that will be used for analysis	12 (See Figure 2)
	12.5		If a composite outcome is used, define all individual components of the composite outcome	N/A
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 Figure)	-	12 (See Figure 2)
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	-	14
	14.1		Define and justify the target difference between treatment groups.(eg, the minimal important difference)	14
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	-	8
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 enroll participants or assign interventions	-	13

Section	Item No.	SPIRIT 2013 Item	SPIRIT-Outcomes 2022 item	Location Reported
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	-	13
Implementation	16c	Who will generate the allocation sequence, who will enroll participants, and who will assign participants to interventions	-	8, 13
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	-	13
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	-	N/A
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	-	10-12 (See Figure 2)
	18a.1		Describe what is known about the responsiveness of the study instruments in a population similar to the study sample	10-12
	18a.2		Describe who will assess the outcome (eg, nurse, parent)	13
	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	-	N/A

Section	Item No.	SPIRIT 2013 Item	SPIRIT-Outcomes 2022 item	Location Reported
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	-	18
Statistical methods	20a	Statistical methods for analyzing primary and secondary outcomes.Reference to where other details of the statistical analysis plan can be found, if not in the protocol	-	13
	20a.1		Describe any planned methods to account for multiplicity in the analysis or interpretation of the primary and secondary outcomes (eg, coprimary outcomes, same outcome assessed at multiple time points, or subgroup analyses of an outcome)	13
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	-	13
	20c	Definition of analysis population relating to protocol non- adherence (eg, as randomized analysis), and any statistical methods to handle missing data (eg, multiple imputation)	-	13
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 detailsabout its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	-	12
	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 thetrial	-	13
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	-	12

Section	Item No.	SPIRIT 2013 Item	SPIRIT-Outcomes 2022 item	Location Reported
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	-	18
Ethics and dissemination				
Research ethics approval	24	Plans for seeking research ethicscommittee/institutional review board (REC/IRB) approval	-	17
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	-	17
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorized surrogates, and how (see Item 32)	-	17
	26b	Additional consent provisions forcollection and use of participant data and biological specimens in ancillary studies, if applicable	-	N/A
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
Declaration of interests	28	Financial and other competing interests for principal investigatorsfor the overall trial and each study site	-	18
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such accessfor investigators	-	18
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	-	N/A
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	-	17
	31b	Authorship eligibility guidelinesand any intended use of professional writers	-	N/A

Section	Item No.	SPIRIT 2013 Item	SPIRIT-Outcomes 2022 item	Location Reported
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	-	17
Appendices				
Informed consent materials	32	Model consent form and other related documentation given to participants and authorized surrogates	-	See Additional File 3
Biological specimens	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	-	N/A

[a]It is strongly recommended that this checklist be read in conjunction with the SPIRIT (Standard Protocol Items: Recommendatio ns for Interventional Trials) Statement paper for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license and is reproduced with permission.
[b]Indicates page numbers and/or manuscript location: to be completed by authors.

Source: Butcher NJ, Monsour A, Mew EJ, et al. Guidelines for reporting outcomes in trial protocols: the SPIRIT-Outcomes 2022extension. JAMA. Published online December 13, 2022. doi:10.1001/jama.2022.21243

Additional file 2 - Questionnaire on computer and internet use

QUESTIONNAIRE ON COMPUTER AND INTERNET USE

(This questionnaire will be completed by the research team during the first telephone contact with the patient).

Patient ID:
Autonomous Community:
Referral health center/hospital:

Please answer the following questions about computer and internet use:

1. What type of device do you own? (Check all that apply):
   · Computer
   · Tablet
   · Laptop
   · Smartphone

   * *To meet the study requirements, patients must have at least one device.*

2. Do you have Internet access on your devices?
   · Yes
   · No

   * *To meet the study requirements, only patients that answer YES could participate.*

3. How often do you use the Internet (including email)?
   · Never
   · Less than once a month
   · Once a month
   · Once or twice a week
   · Everyday

   * *To meet the study requirements, patients who check ONE OF THE FIRST TWO BOXES will not be able to participate.*

4. When you are online, which of the following activities do you do? (check all that apply):
   · I check the email
   · Web surfing / Searching information
   · Shopping / User accounts payment
   · I play video games
   · I download or listen to music
   · I watch videos or movies
   · I use social networks (e.g. Facebook, Instagram, Twitter, Snapchat, Telegram,...)
   · I send instant messages (e.g. Skype, WhatsApp, Facebook Messenger, Telegram..)
   · I read press news

· I take courses or distance studies
· Use of different Apps

** To meet the study requirements, patients must check AT LEAST 3 BOXES to participate.*

Additional file 3 - Informed consent

Patient information sheet

Clinical trial

INTRODUCTION

Dear Sir or Madam,

We would like to inform you that we are implementing the clinical trial entitled "Effectiveness and cost-effectiveness of a virtual Community of Practice (CdPV web application) for improving the empowerment of middle-aged individuals with multimorbidity: RCT".

This is a multicenter project involving Madrid: PI22/01124, the project coordinator, and the Canary Islands: PI22/00691.

This study has been approved by the Ethics Committees for Clinical Research of the participating centers in accordance with current legislation, Organic Law 3/2018, of December 5, on the Protection of Personal Data and the Guarantee of Digital Rights, and the application of Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016. Here you will find the correct and sufficient information to evaluate and decide whether or not you want to participate in this study. To do so, please read this information sheet carefully, and we will clarify any doubts that may arise after the explanation. Furthermore, you may consult with anyone you deem appropriate.

Voluntary participation

You should be aware that your participation in this study is voluntary, and you have the right to choose not to participate or change your decision and withdraw your consent at any time. Your decision will not affect your relationship with your doctor, nor will it cause any harm to your treatment.

Who are the researchers?

The research team is a multidisciplinary group of professionals, including medical doctors, psychologists, statisticians, healthcare service evaluators, general practitioners, nurses, and cardiologists. The team members are affiliated with the following institutions: Avedis Donabedian Foundation, Primary Care Management, and the Directorate General of Research, Teaching, and Innovation of the Ministry of Health of the Community of Madrid, as well as the Service for the Evaluation of the Canary Islands Health Service (SESCS).

STUDY DESCRIPTION

Why is this study being conducted?

The purpose of this study is to evaluate the effectiveness of a virtual Community of Practice (VCoP) for middle-aged individuals with multiple chronic diseases. We aim to improve their knowledge, skills, and self-confidence in managing their own health. This will be measured using the specific Patient Activation Measure (PAM) questionnaire, which assesses activation levels in individuals with chronic diseases, at 12-months, comparing it with the active control group.

Who can participate?

If you are between 30 and 60 years old, have been diagnosed with two or more chronic diseases, and have internet access at home and/or a smartphone, you are eligible to participate.

Study procedure:

There will be two study groups: the Intervention Group (GI) and the Control Group (GC). Participants will be randomly assigned to one of these groups. If you decide to participate in the study, you could be placed in either group.

If you choose to participate, what does your involvement entail?

The study will last for 18 months. At the beginning of the study and at 6, 12, and 18 months, participants will complete online questionnaires. These questionnaires will assess various aspects related to each participant's level of activation in health-related decisions (PAM questionnaire), depression using the self-administered Patient Health Questionnaire-9 (PHQ-9), anxiety using the self-administered Hospital Anxiety and Depression Scale - Anxiety Subscale (HADS-A), treatment burden using the self-administered Treatment Burden Questionnaire (TBQ), and health-related quality of life using the self-administered E5-5D-5L questionnaire (EuroQol group). Completing these questionnaires will take approximately 30 minutes.

During the baseline visit, sociodemographic variables and other variables related to your chronic diseases and treatment will be collected. If necessary, access to your medical history may be granted to verify this information.

If you are randomly assigned to the IG, you will be offered the opportunity to participate for 18 months in a Virtual Community of Practice (VCoP) based on a web 2.0 platform. A registration link will be provided to you via email to initiate your voluntary participation.

In the Virtual Community of Practice (VCoP), you will have access to leisure and educational activities based on strategies that facilitate learning, as well as the exchange of knowledge and experiences among participants and a multidisciplinary team of professionals. Various topics related to health competencies, self-efficacy techniques, lifestyle, acceptance of chronic illness, and shared decision-making will be addressed.

If you are randomly assigned to the CG, you will continue to receive the standard care and attention provided in regular clinical practice. Additionally, you will be offered the same educational content as the intervention group but self-administered.

Benefits and risk of participating in this study.

There are no anticipated physical or psychological risks associated with participating in this study. The main benefit for participants with multiple chronic diseases is the opportunity to improve their knowledge, skills, and self-confidence in managing their own health and healthcare.

Confidentiality

The processing, communication, and transfer of personal data of all participating individuals will comply with the provisions of Organic Law 3/2018, of December 5, on the Protection of Personal Data and Guarantee of Digital Rights, and the application of Regulation (EU) 2016/679 of the European Parliament and of the Council of April 27, 2016, on the Protection of Personal Data (GDPR). It is important that you are aware of the following information:

In addition to the rights, you are already familiar with (access, modification, objection, and cancellation of data), you now also have the right to limit the processing of incorrect data, request a copy of the data you have provided for the study, or have them transferred to a third party (data portability). Similarly, you have the right to withdraw your consent for data processing; however, such withdrawal may result in your discontinuation of participation in the trial. To exercise your rights, please contact the principal investigator of the study. Please note that data cannot be deleted even if you discontinue participation in the trial or withdraw your consent for data processing, to ensure the validity of the research and comply with legal obligations and medication authorization requirements. You also have the right to file a complaint with the Data Protection Agency if you are not satisfied.

Altogether, the Center, the Sponsor, and the Investigator are each responsible for your data processing and are committed to comply with current data protection regulations. The data collected for the study will be identified using a code, so that no information

that can identify you is included. Only your study doctor/collaborators will be able to link this data to you and your medical history. Therefore, your identity will not be disclosed to anyone else unless required by health authorities or in cases of medical emergency. The Research Ethics Committees, representatives of the Health Authority responsible for inspection, and authorized personnel from the Sponsor may access personal data to verify the study procedures and compliance with good clinical practice standards (always maintaining the confidentiality of the information).

The Investigator and the Sponsor are obligated to retain the data collected for the study for at least 25 years after its completion. Afterwards, your personal information will only be retained by the healthcare center for your health care purposes and by the Sponsor for other scientific research purposes if you have provided consent for such retention, and if allowed by law and applicable ethical requirements.

Additional information

As required by law, you will need to sign and date the informed consent document to participate.

Project coordinator. Principal investigator. (Madrid):

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Principal investigator (CANARIAS):

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

Contact: lperperr@gobiernodecanarias.org

Informed consent for patients

(name and surname) declares:

.....

That I have read the Patient information sheet.

That I could make any questions regarding the study

That I have enough information about the study

I received this information from:

.....

I understand that my participation is volunteer, and I can withdraw it:

1. Whenever I want.
2. I don't have to give any explanations.
3. Without any repercussions for my healthcare.

- I freely give my consent to participate in the study and authorize the access and use of my data under the conditions detailed in the information sheet.

Name of the participant:

Date: Signature:

Investigator name:

Date: Signature:

Additional file 4 - O'Halloran list

CHAP	ICPC-2 RUBRIC	DESCRIPTION	ICPC-2 PLUS CODE	DESCRIPTION
A	*A04*	*Weakness/Tiredness general*	*029*	*Chronic fatigue syndrome*
			031	*Myalgic encephalomyelitis*
			030	*Post viral fatigue syndrome*
			028	*Post viral syndrome*
	A70	Tuberculosis		
	A79	Malignancy, NOS		
	A90	Congenital anomaly NOS/multiple		
B	B72	Hodgkin's disease/lymphoma		
	B73	Leukaemia		
	B74	Malignant neoplasm blood other		
	B75	*Benign/unspecified neoplasm blood*	*008*	*Myelodysplastic syndrome*
			004	*Polycythaemia rubra vera*
	B78	Hereditary haemolytic anaemia		
	B81	Anaemia, Vit B12/folate deficiency		
	B82	Anaemia, other/unspecified		
	B83	Purpura/coagulation defects		
	B90	HIV infection/AIDS		
D	*D72*	*Viral hepatitis*	*003*	*Hepatitis B*
			008	*Hepatitis C*
			009	*Hepatitis D*
	D74	Malignant neoplasm stomach		
	D75	Malignant neoplasm colon/rectum		
	D76	Malignant neoplasm pancreas		

CHAP	ICPC-2 RUBRIC	DESCRIPTION	ICPC-2 PLUS CODE	DESCRIPTION
	D77	Malignant neoplasm digestive other/NOS		
	D81	*Congenital anomaly digestive system*	*011*	*Atresia;biliary*
			005	*Cleft;palate/lip*
			007	*Disease;Hirschsprungs*
			002	*Harelip*
			001	*Megacolon;congenital*
	D84	Congenital anomaly digestive system		
	D85	Duodenal ulcer		
	D86	Peptic ulcer other		
	D92	Diverticular disease		
	D93	Irritable bowel syndrome		
	D94	Chronic enteritis/ulcerative colitis		
	D97	Liver disease NOS		
	D98	Cholecystitis/cholelithiasis		
	D99	*Disease digestive system, other*	*029*	*Blind loop syndrome*
			032	*Insufficiency;pancreatic*
			017	*Insufficiency;vascul;mesentery*
			013	*Gluten sensitivity*
			015	*Intolerance;fat*
			012	*Intolerance;gluten*
			054	*Intolerance;lactose*
			028	*Malabsorption syndrome*
			043	*Pancreatitis*
			036	*Pyloric stenosis;acquired*
			024	*Sprue*
			055	*Stenosis;anal*

CHAP	ICPC-2 RUBRIC	DESCRIPTION	ICPC-2 PLUS CODE	DESCRIPTION
			025	*Stenosis;sigmoid colon*
			016	*Thrombosis;mesenteric*
F	*F74*	*Neoplasm of eye/adnexa*	*003*	*Carcinoma;eye*
			002	*Neoplasm malig;eye*
	F83	Retinopathy		
	F84	Macular degeneration		
	F92	Cataract		
	F93	Glaucoma		
	F94	Blindness		
H	*H75*	*Neoplasm of ear*	*003*	*Carcinoma;ear*
			002	*Neoplasm malig;ear*
	H82	Vertiginous syndrome		
	H84	Presbyacusis		
	H86	Deafness		
K	*K71*	*Rheumatic fever/heart disease*	*010*	*Carditis;rheumatic;chronic*
			012	*Myocarditis;rheumatic;chronic*
			015	*Stenosis;arterial;rheumatic*
			005	*Stenosis;mitral;rheumatic*
	K72	*Neoplasm, cardiovascular*	*003*	*Carcinoma;cardiovascular*
			002	*Neoplasm malig;cardiovascular*
	K73	Congenital anomaly, cardiovascular		
	K74	Ischaemic heart disease with angina		
	K75	Acute myocardial infarction		
	K76	Ischaemic heart disease without angina		
	K77	Heart failure		

CHAP	ICPC-2 RUBRIC	DESCRIPTION	ICPC-2 PLUS CODE	DESCRIPTION
	K78	Atrial fibrillation/flutter		
	K79	Paroxysmal tachycardia		
	K80	Cardiac arrhythmia NOS		
	K81	Heart/arterial murmur NOS		
	K82	Pulmonary heart disease		
	K83	Heart valve disease NOS		
	K84	Heart disease, other		
	K86	Hypertension, uncomplicated		
	K87	Hypertension, complicated		
	K88	Postural hypotension		
	K89	Transient cerebral ischaemia		
	K90	Stroke/cerebrovascular accident		
	K91	Cerebrovascular disease		
	K92	Atherosclerosis/peripheral vascular disease		
	K93	Pulmonary embolism		
	K94	Phlebitis/thrombophlebitis		
	K95	Varicose veins of leg		
L	L71	Malignant neoplasm, musculoskeletal		
	L82	*Congenital anomaly, musculoskeletal*	*001*	*Achondroplastic dwarf*
			003	*Clubfoot*
			015	*Curvature of spine;congenital*
			025	*Deformity;foot;congenital*
			024	*Dislocation;hip;congenital*
			013	*Ehlers Danlos syndrome*
			021	*Kyphoscoliosis;congenital*

CHAP	ICPC-2 RUBRIC	DESCRIPTION	ICPC-2 PLUS CODE	DESCRIPTION
			019	*Kyphosis;congenital*
			007	*Lordosis;congenital*
			018	*Osteogenesis imperfecta*
			027	*Plagiocephaly*
			012	*Scoliosis;congenital*
			014	*Talipes*
	L83	Neck syndrome		
	L84	Back syndrome without radiating pain		
	L85	Acquired deformity of spine		
	L86	Back syndrome with radiating pain		
	L88	Rheumatoid/seropositive arthritis		
	L89	Osteoarthritis of hip		
	L90	Osteoarthritis of knee		
	L91	Osteoarthritis, other		
	L92	Shoulder syndrome		
	L93	Tennis elbow		
	L95	Osteoporosis		
	L99	*Musculoskeletal disease, other*	*047*	*Arthropathy;Behcets syndrome*
			087	*Arthropathy;Reiters disease*
			088	*Chondromalacia;patella*
			013	*Disease;Pagets (bone)*
			093	*Dystrophy;muscular*
			056	*Lupus erythematosus*
			025	*Osteitis*
			026	*Osteitis deformans*
			060	*Polymyositis*

CHAP	ICPC-2 RUBRIC	DESCRIPTION	ICPC-2 PLUS CODE	DESCRIPTION
			071	*Progressive system sclerosis*
			075	*Reiters syndrome*
			078	*Repetitive Strain Injury*
			069	*Scleroderma;diffuse*
			070	*Scleroderma;localised*
			028	*Scleroderma;progressive*
			033	*Sjorgens syndrome*
			065	*Systemic lupus erythematosus*
N	N73	Neurological infection, other		
	N74	Malignant neoplasm nervous system		
	N75	Benign neoplasm nervous system		
	N76	Neoplasm nervous system, unspecified		
	N85	Congenital anomaly neurological		
	N86	Multiple sclerosis		
	N87	Parkinsonism		
	N88	Epilepsy		
	N89	Migraine		
	N90	Cluster headache		
	N92	Trigeminal neuralgia		
	N93	Carpal tunnel syndrome		
	N94	Peripheral neuritis/neuropathy		
	N99	*Neurological disease, other*	*025*	*Arachnoiditis*
			005	*Atrophy;cerebral*
			004	*Chorea;Huntingtons*
			027	*Degeneration;cerebral*
			010	*Disease;motor neuron*

CHAP	ICPC-2 RUBRIC	DESCRIPTION	ICPC-2 PLUS CODE	DESCRIPTION
			042	*Encephalopathy*
			043	*Encephalopathy;Wernickes*
			011	*Myasthenia Gravis*
			003	*Palsy;cerebral*
			022	*Palsy;infantile spastic*
			040	*Palsy;spastic*
			017	*Paralysis;infantile spastic*
			018	*Paraplegia*
			020	*Quadriplegia*
			030	*Syringomyelia*
P	P15	Chronic alcohol abuse		
	P70	Dementia		
	P71	Organic psychosis, other		
	P72	Schizophrenia		
	P73	Affective psychosis		
	P74	Anxiety disorder/anxiety state		
	P75	Somatisation disorder		
	P76	Depressive disorder		
	P78	Neuraesthenia, surmenage		
	P79	Phobia/compulsive disorder		
	P80	Personality disorder		
	P81	Hyperkinetic disorder		
	P82	Post-traumatic stress disorder		
	P85	Mental retardation		
	P86	Anorexia nervosa/bulimia		
	P98	Psychosis NOS/other		

CHAP	ICPC-2 RUBRIC	DESCRIPTION	ICPC-2 PLUS CODE	DESCRIPTION
	P99	*Psychological disorders, other*	*005*	*Autism*
			006	*Autism;child*
R	R84	Malignant neoplasm bronchus, lung		
	R85	Malignant neoplasm respiratory, other		
	R90	Hypertrophy tonsils/adenoids		
	R95	Chronic obstructive pulmonary disease		
	R96	Asthma		
	R99	*Respiratory disease, other*	*015*	*Asbestosis*
			018	*Bronchiectasis*
			004	*Failure;respiratory*
			009	*Farmers lung*
			019	*Fibrosing alveolitis*
			010	*Fibrosis;pulmonary*
			012	*Pneumoconiosis*
			020	*Pneumonia;interstitial*
S	S77	Malignant neoplasm of skin		
	S86	Dermatitis, seborrhoeic		
	S87	Dermatitis/atopic eczema		
	S91	Psoriasis		
	S96	*Acne*	*007*	*Acne*
			003	*Acne;conglobulate (cystic)*
			002	*Acne;vulgaris*
	S99	*Skin disease, other*	*001*	*Acne;rosacea*
			003	*Dermatitis;herpetiformis*
			034	*Discoid lupus erythematosus*
			042	*Lichen sclerosus*

CHAP	ICPC-2 RUBRIC	DESCRIPTION	ICPC-2 PLUS CODE	DESCRIPTION
			031	*Necrobiosis lipoidica diabetic*
			018	*Pemphigus*
			021	*Rhinophyma*
T	T71	Malignant neoplasm thyroid		
	T73	*Neoplasm endocrine other/uncertain*	*001*	*Carcinoma;endocrine*
			002	*Neoplasm malig;endocrine*
	T80	*Congenital anomaly endocrine/metabolic*	*007*	*Cretinism*
			001	*Disease;Hurlers*
			002	*Dwarfism*
			005	*Pseudohypoparathyroidism*
	T81	Goitre		
	T82	Obesity		
	T83	Overweight		
	T85	Hyperthyroidism/thyrotoxicosis		
	T86	Hypothyroidism/myxoedema		
	T89	Diabetes, insulin dependent		
	T90	Diabetes, non-insulin dependent		
	T92	Gout		
	T93	Lipid disorder		
	T99	*Endocrine/metabolic/nutritional disease, other*	*001*	*Acromegaly*
			006	*Amyloidosis*
			028	*Cushings syndrome*
			053	*Cystic fibrosis*
			011	*Diabetes insipidus*
			002	*Disease;Addisons*

CHAP	ICPC-2 RUBRIC	DESCRIPTION	ICPC-2 PLUS CODE	DESCRIPTION
			064	*Disease;fibrocystic*
			013	*Disease;Gilberts*
			018	*Disease;Hashimotos*
			046	*Disease;Wilsons*
			035	*Haemochromatosis*
			073	*Homocystinuria*
			036	*Hyperaldosteronism*
			037	*Hyperparathyroidim*
			069	*Hyperprolactinaema*
			030	*Hypoparathyroidism*
			023	*Phenylketonuria*
			043	*Polycystic ovary syndrome*
			026	*Porphyria*
			040	*Stein Leventhal syndrome*
			041	*Thyroiditis*
U	U75	Malignant neoplasm kidney		
	U76	Malignant neoplasm bladder		
	U77	Malignant neoplasm, urinary, other		
	U88	Glomerulonephritis/nephrosis		
	U99	*Urinary disease, other*	*019*	*Diverticulitis;bladder*
			023	*Failure;renal;chronic*
			022	*Insufficiency;renal*
			006	*Necrosis;renal*
			024	*Necrosis;renal;papillary*
			013	*Reflux;ureteric*
			028	*Stenosis;artery;renal*

CHAP	ICPC-2 RUBRIC	DESCRIPTION	ICPC-2 PLUS CODE	DESCRIPTION
			017	*Stenosis;urethral*
W	W15	Infertility/subfertility		
	W72	Malignant neoplasm related to fertility		
X	X74	Pelvic inflammatory disease		
	X75	Malignant neoplasm cervix		
	X76	Malignant neoplasm breast female		
	X77	Malignant neoplasm genital female other		
	X99	*Genital disease, other*	*016*	*Endometriosis*
			009	*Fistula;vaginal*
Y	Y77	Malignant neoplasm prostate		
	Y78	Malignant neoplasm male genital, other		
	Y85	Benign prostatic hypertrophy		

N.B. Italics indicate that the ICPC-2 rubric is chronic only at the ICPC-2 PLUS level. Conditions listed in the 'ICPC-2 PLUS Code' column are those within the rubric which have been labelled as chronic using the extended terminology of ICPC-2 PLUS.

Source: O'Halloran J, Miller GC, Britt H. Defining chronic conditions for primary care with ICPC-2. Family Practice [Internet]. 2004 Aug 1;21(4):381–6.

DICTAMEN DEL COMITÉ de ÉTICA DE LA INVESTIGACIÓN con MEDICAMENTOS

D. Roberto Collado Borrell, Secretario Técnico del **COMITÉ de ÉTICA DE LA INVESTIGACIÓN con MEDICAMENTOS HOSPITAL GENERAL UNIVERSITARIO GREGORIO MARAÑÓN**

CERTIFICA

Que se ha evaluado la propuesta del promotor referida al estudio observacional:

Código PI22/01124
TÍTULO: "Efectividad y coste-efectividad de una Comunidad de Práctica virtual (CdPV aplicación web) para la mejora del empoderamiento de personas de mediana edad con multimorbilidad: ECA"
Protocolo versión 2. 29 de mayo de 2023. **Hoja de Información al paciente y Consentimiento Informado Fase Ensayo Clínico** versión 3. 7 de junio de 2023. **Hoja de Información al paciente y Consentimiento Informado Fase Co-Diseño** versión 1. 20 de marzo de 2023.
Promotor: Investigador

- El estudio se plantea siguiendo los requisitos legalmente establecidos, y su realización es pertinente.
- Se cumplen los requisitos necesarios de idoneidad del protocolo en relación con los objetivos del estudio y están justificados los riesgos y molestias previsibles para el sujeto.
- Es adecuado el procedimiento para obtener el consentimiento informado
- El alcance de las compensaciones económicas previstas no interfiere con el respeto a los postulados éticos.
- La capacidad del investigador y sus colaboradores, y las instalaciones y medios disponibles, tal y como ha sido informado, son apropiados para llevar a cabo el estudio.

Este CEIm actuando como comité evaluador, emite **dictamen favorable** y acepta que dicho estudio sea realizado en los centros siguientes por los investigadores principales que se relacionan a continuación:

Dra. Ana Isabel González González / Unidad de Innovación y Proyectos Internacionales - Consejería de Sanidad de la Comunidad de Madrid

Y HACE CONSTAR QUE:

1º En la reunión celebrada el día **05 de junio de 2023**, **acta 11/2023** se decidió emitir el informe correspondiente al estudio de referencia.
2º En dicha reunión se cumplieron los requisitos establecidos en la legislación vigente -Real Decreto 1090/2015 y Decreto 39/94 de la Comunidad de Madrid- para que la decisión del citado CEIm sea válida.
3º El CEIm, tanto en su composición, como en los PNT cumple con las normas de BPC (CPMP/ ICH/ 135/95)
4º La composición actual del CEIm es la siguiente:

D. ANDRÉS JESÚS MUÑOZ MARTÍN (Oncología Médica - Presidente)
Dª. MARÍA LUISA NAVARRO GÓMEZ (Pediatría - Vicepresidenta)
D. ROBERTO COLLADO BORRELL (Farmacia Hospitalaria – Secretario Técnico)
D. JUAN ANTONIO ANDUEZA LILLO (Medicina Interna)
Dª. BEATRIZ AUDIBERT AMOROTO (Licenciada en Derecho)
Dª. MARÍA LUISA BAEZA OCHOA DE OCÁRIZ (Alergología)
Dª. PILAR AITANA CALVO FERRÁNDIZ (Farmacología Clínica)
Dª. ISABEL CASTREJÓN FERNÁNDEZ (Reumatología)
Dª MARÍA DEL CARMEN DE LA CRUZ ARGUEDAS (Unidad de Apoyo a la Investigación)
D. VICENTE DE LAS PEÑAS GIL (Psicología Clínica)
D. JAVIER DE MIGUEL DÍEZ (Neumología)
Dª. PATRICIA FONT LÓPEZ (Hematología y Hemoterapia)
Dª. ISABEL GÓMEZ VALBUENA (Farmacia de Atención Primaria)
D. PABLO GONZÁLEZ NAVARRO (Bioestad´sitica)
Dª. MARÍA DEL CARMEN HERAS ESCOBAR (Enfermería)
Dª. LUIS IBÁÑEZ SAMANIEGO (Digestivo)
Dª. ANA MARÍA IGLESIAS MOHEDANO (Neurología)
D. LUIS ANDRÉS LÓPEZ FERNÁNDEZ (Biología)
Dª. ANA ESTHER LÓPEZ PÉREZ (Anestesiología y Reanimación)
D. ANTONIO MUIÑO MIGUEZ (Medicina Interna)
Dª. SARA PÉREZ RAMÍREZ (Oncología)
D. JOSÉ LUIS REVUELTA HERRERO (Farmacia Hospitalaria)
D. EDUARDO ZATARAÍN NICOLÁS (Cardiología)

Lo que firmo en Madrid, a 07 de junio de 2023

Fdo.: Dr. Roberto Collado Borrell

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Servicio Canario de la Salud

Gobierno de Canarias

El estudio de investigación titulado: "**Efectividad y coste-efectividad de una Comunidad de Práctica Virtual (CdPV aplicación web) para la mejora del empoderamiento de personas de mediana edad con multicomorbilidad: ECA**", versión **1_19012023,** con código **CHUNSC_2023_06**, del que es Investigador Principal la Dra. LILISBETH PERESTELO PEREZ, ha sido evaluado por el Comité de Ética de la Investigación con medicamentos del Complejo Hospitalario Universitario de Canarias (Provincia de Santa Cruz de Tenerife) en su sesión del **26/01/2023**, y considera que:

Se cumplen los requisitos necesarios de idoneidad del Protocolo con los objetivos del estudio.

El procedimiento para obtener el consentimiento informado, incluyendo la hoja de información para los sujetos y el consentimiento informado, **versión 2, 13-03-2023** y la hoja de información al profesional y el consentimiento informado, **versión 2, 13-02-2023,** es adecuado.

La capacidad del Investigador y los medios disponibles son adecuados para llevar a cabo el estudio y no interfiere con el respeto a los postulados éticos.

Por todo ello, el Comité de Ética de la Investigación con medicamentos del Complejo Hospitalario Universitario de Canarias (Provincia de Santa Cruz de Tenerife) emite dictamen **FAVORABLE** para la realización de este estudio en el Servicio de Evaluación del Servicio Canario de la Salud (SESCS).

Secretario Técnico en funciones del CEIm
Complejo Hospitalario Universitario de Canarias

Servicio Canario de la Salud

Gobierno de Canarias

INFORMACIÓN ADICIONAL:

Es responsabilidad del investigador principal garantizar que todos los investigadores asociados con este proyecto conozcan las condiciones de aprobación y los documentos aprobados.

El Investigador Principal debe informar a la Secretaría del CEIm mediante una enmienda, informe anual de seguimiento o notificación, de:

• Cualquier cambio significativo en el proyecto y la razón de ese cambio, incluida una indicación de las implicaciones éticas (si las hubiera);
• Eventos adversos graves en los participantes y la acción tomada para abordar esos efectos;
• Cualquier otro evento imprevisto o inesperado, como desviaciones de protocolo;
• El cambio de Investigador Principal;
• Informe anual de seguimiento;
• La fecha de finalización del estudio;
• Informe final del estudio y/o publicación de resultados.

BMJ Open

Implementation of a virtual community of practice to promote the empowerment of middle-aged people with multimorbidity: Study protocol of a randomized controlled trial.

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2024-084937.R1
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Complete List of Authors:	Campillejo, Alba; Community of Madrid Madrid Health Service, Foundation for Biosanitary Research and Innovation in Primary Care Gefaell-Larrondo, Ileana; Community of Madrid Madrid Health Service, Foundation for Biosanitary Research and Innovation in Primary Care Ramos-García, Vanesa; Canary Islands Health Service, Canary Islands Health Research Institute Foundation Koatz, Débora; Autonomous University of Barcelona, Avedis Donabedian Research Institute (FAD); Research Network on Chronicity Primary Care and Prevention and Health Promotion Santos-Álvarez, Anthea; Canary Islands Health Service, Canary Islands Health Research Institute Foundation Barrio-Cortes, Jaime; Community of Madrid Madrid Health Service, Foundation for Biosanitary Research and Innovation in Primary Care Gómez-Rueda, Sara; Community of Madrid Madrid Health Service, Gregorio Marañón Research Institute Calderón-Larrañaga, Amaia; Karolinska Institutet Cifuentes, Patricia; Community of Madrid Ministry of Health, University Hospital of Alcorcón Company-Sancho, Consuelo; Canary Islands Health Service, General Directorate of Ublic Health Domínguez-Coello, Santiago; Canary Islands Health Service, La Laguna Health Care Center - Family and Community Care teaching unit García-García, Francisco Javier; Canary Islands Health Service, Quality Care Unit - Nuestra Señora de La Candelaria University Hospital (HUNSC) Garrido-Elustondo, Sofía; Comunidad de Madrid Consejeria de Sanidad, Centre Family and Community Care Teaching Multiprofessional Unit González de León, Beatriz; Canary Islands Health Service, Tenerife Primary Care Management Ramón-Vazquez, José; Canary Islands Health Service, Tenerife Primary Care Management Martín, Candelaria; Hospital Universitario de Canarias, Internal Medicine Department Suárez-Fernández, Carmen; Community of Madrid Madrid Health Service, La Princesa Hospital Parra-Caballero, Pedro; Community of Madrid Madrid Health Service, La Princesa Hospital Vicente-Rabaneda, Esther F.; Community of Madrid Madrid Health Service, La Princesa Hospital

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Primary Subject Heading:	General practice / Family practice
Secondary Subject Heading:	Health services research
Keywords:	Self-Management, Chronic Disease, Clinical Trial, Community-Based Participatory Research, GENERAL MEDICINE (see Internal Medicine)

TITLE PAGE

TITLE

Implementation of a virtual community of practice to promote the empowerment of middle-aged people with multimorbidity: Study protocol of a randomized controlled trial.

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ABSTRACT

Introduction

Empowering people living with multimorbidity (multiple chronic conditions) to gain greater confidence in managing their health can enhance their quality of life. Education focused on self-management is a key tool for fostering patient empowerment and is mostly provided on an individual basis. Virtual Communities of Practice (VCoP) present a unique opportunity for online education in chronic condition self-management within a social context. This research aims to evaluate the effectiveness/cost-effectiveness of individualized, online self-management education compared to VCoP among middle-aged individuals living with multiple chronic conditions.

Methods and analysis

People aged 30-60, living with ≥2 chronic conditions, and receiving care in primary care centers and outpatient hospital-based clinics in Madrid and Canary Islands will enroll in an 18-month parallel-design, blinded (intervention assessment and data analysts), pragmatic (adhering to the intention-to-treat principle), individually randomized trial. The trial will compare two 12-month web-based educational offers of identical content; one delivered individually (control) and the other with online social interaction (VCoP, intervention). Using repeated measures mixed linear models, with the patient as random effect and allocation groups and time per group as fixed effects, we will estimate between-arm differences in the change in Patient Activation Measure (PAM) from baseline to 12 months (primary endpoint), including measurements at 6- and 18-months follow-up. Other outcomes will include measures of depression and anxiety, treatment burden, quality of life. In addition to a process evaluation of the VCoP, we will conduct an economic evaluation estimating the relative cost-effectiveness of the VCoP from the perspectives of both the National Health System and the Community.

Ethics and Dissemination

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

Trial registration: ClinicalTrials.gov. NCT06046326

STRENGTHS AND LIMITATIONS OF THIS STUDY

Strengths

- Pragmatic, multicenter design enhances the generalizability of the findings.
- Comprehensive measures, including patient activation, mental health, and quality of life.
- Longitudinal follow-up over 18 months to assess interventions' sustained effects.

Limitations

- Restricted to internet-accessible participants, impacting representativeness.
- Dependent on participants' engagement willingness in online communities.

INTRODUCTION

Multimorbidity is defined as the simultaneous presence of two or more chronic conditions in the same individual (1). Multimorbidity is becoming increasingly prevalent globally (2). While the prevalence of multimorbidity tends to rise with age (2), it is worth noting that more than 50% of individuals living with multiple chronic diseases are under the age of 65 (3–5).

Irrespective of age, individuals with multimorbidity tend to have a lower quality of life (6), use more healthcare services (7), and die younger (8) than people living with no or one chronic condition. However, how multimorbidity affects daily life may differ between middle-aged and older people.

It is in middle age when most chronic diseases first manifest. For middle-aged individuals with multimorbidity, the challenge lies in juggling the work of self-management with professional careers, childcare, eldercare, and leisure (9). Healthcare research has not adequately addressed the consequences of multimorbidity, in terms of an individual's capacity for self-care and the significant disruptions to family life, leisure, and community and professional commitments (10,11). Comprehensive, patient-centered strategies to address both medical and psychosocial aspects of care are urgently needed for middle-aged adults living with multimorbidity (12).

Empowerment is the process by which individuals gain control over managing the conditions of their daily life. Empowered individuals take actions to enhance their quality of life and possess the necessary knowledge, skills, attitudes, and self-perception to adapt their behavior and collaborate with others when required to achieve optimal well-being (13). There is a need for effective interventions that promote empowerment, self-confidence, self-esteem, and the ability to cope with the profound implications of multiple chronic diseases.

According to Wenger et al. (14), a Community of Practice (CoP) is a group of individuals engaged in a common activity who develop a shared identity, deepen their knowledge, and expand their experiences in a particular field through ongoing interactions that strengthen their relationships. A group of people sharing the common condition of multimorbidity may benefit from an intervention where they can interact, exchange knowledge, resources, information, and receive mutual and professional support.

Virtual Communities of Practice (VCoP) offer widespread access to information and opportunities for interaction among people facing similar situations, which is particularly valuable for individuals with chronic conditions. Unlike passive educational strategies, key benefits of VCoPs encompass receiving and providing information, offering social support, boosting patient optimism, improving coping skills, brightening mood, reducing anxiety, and managing stress more effectively (15,16).

METHODS AND ANALYSIS

Aim

The main objective of this study is to assess the effectiveness and cost-effectiveness of two online self-management programs for chronic diseases. The first is delivered through a VCoP, fostering a community-based approach (intervention), while the second is provided on an individual basis (control). Other secondary objectives will be taken into account.

Trial design

We will conduct an 18-month, pragmatic, multicenter, parallel, randomized controlled trial. See Additional file 1 for SPIRIT checklist.

Study setting

Both groups will receive the intervention online as an add-on to their usual care at primary care practices and outpatient hospital-based clinics in Madrid and the Canary Islands, Spain.

Eligibility criteria and study population

Patients aged 30-60 and diagnosed with two or more chronic conditions will be identified by their healthcare providers (primary care and hospital physicians and nurses) and proposed to be screened by the research team for the following eligibility criteria:

Inclusion Criteria

1. Age 30 - 60 years.
2. Documentation of at least two chronic diseases in the electronic medical record (EMR) at the time of inclusion.
3. Access to the internet at home or via a smartphone.
4. Ability to meet the study requirements [e.g., digital literacy questionnaire (Additional file 2 shows this in more details)].
5. Signed, written, informed consent.

Exclusion Criteria

1. Institutionalized individuals.
2. Receiving Palliative care.
3. Telephone/email contact information missing from clinic databases.

Recruitment and Implementation Strategies for Health Care Providers in Madrid and Canary Islands.

Recruitment Process

Health care providers (HCPs) from Madrid and the Canary Islands will be invited to participate in recruiting subjects for the study. To facilitate this process, the research team will conduct informative sessions with HCPs, including nurses and physicians from outpatient clinics and primary care centers. These sessions will focus on detailing the project's objectives, outlining specific recruitment guidelines, and describing the responsibilities involved. Interested HCPs will then approach eligible patients, based on predefined inclusion criteria, to introduce them to the study's aims and requirements.

Patient Engagement and Information Dissemination

Patients expressing interest in the study will be contacted by a member of the researcher team. This step involves providing comprehensive information about the study, addressing any queries, and assessing the patients' familiarity with computer and internet usage. Following this, patients will gain access to a specialized web platform, designed exclusively for this project. This platform houses the informed consent document, which participants are required to understand and sign before proceeding. Subsequently, participants will complete baseline questionnaires, after which they will receive a one-year access to their assigned implementation strategy. For data management the patient ID will be anonymized. The study's flow-chart can be found in Figure 1.

Implementation Strategies Overview

To define the interventions, we used the taxonomy of self-management interventions for chronic diseases developed by Orrego et al. (17):

1) Intervention Group – "e-mpoderaT" Platform:

- Platform Features: A gamified Virtual Community of Practice (VCoP), hosted on a Web 2.0 platform, will encourage the sharing of experiences and knowledge through

collective learning (16). The platform will provide diverse educational and interactive content, including forums, readings, resources, videos, games, and virtual sessions, all aimed at enhancing self-care and promoting knowledge exchange.

- Customization and Support: Tailored to address the unique needs of people with multimorbidity, this intervention will be co-created with patients and HCPs, leading to the development of a "Patient Journey Map". A healthcare professional experienced in facilitating patient groups will moderate the VCoP, ensuring active engagement, addressing queries, and fostering communication with a multidisciplinary team of experts, including general practitioners, cardiologists, psychologists, and nutritionists.
- Educational Focus: The content emphasizes patient empowerment dimensions like health competence, behavioral change, symptom monitoring, and shared decision-making, aligning with European guidelines for managing chronic diseases (16).

2) Control Group – Standard Care with Educational Access:

- Usual Care and Educational Resources: Participants in the control group will continue receiving standard care in line with local guidelines. Additionally, they will have access to a self-administered platform featuring the same educational content as the VCoP, minus the interactive and engagement components.

Table 1 summarizes the implementation strategy.

Description of materials and outcome measures

Primary outcome

The primary outcome will be the level of patient activation, assessed using the Patient Activation Measure (PAM) questionnaire (18,19). Higher levels of patient activation, as measured by the PAM are linked to greater patient satisfaction, better quality of life, and enhanced physical and mental functional status (18). This questionnaire consists of 13 items

that evaluate knowledge, skills, and confidence for self-care in patients with chronic conditions. Responses are measured on a Likert 1–4-point scale, resulting in a total score ranging from 0 to 100, with 100 indicating the highest level of patient activation. The Spanish-translated version has been validated in patients with chronic diseases and exhibits good validity and reliability properties (20). The e-mpoderaT research team has previously employed this questionnaire in their studies (e-mpodera (21) and e-mpodera2 (22)).

Secondary outcomes

- *Depression*: The Patient Health Questionnaire-9 (PHQ-9) (23) will be used to detect depression, characterize its severity (24), and support follow-up (25). Validated in Spanish (26), it consists of 9 items that assess the presence of depressive symptoms in the last 2 weeks. Each item has a severity index: 0 = "never", 1 = "some days", 2 = "more than half the days" and 3 = "almost every day". A score between 0–4 indicates no depressive symptoms, 5–9 mild depressive symptoms, 10–14 moderate depressive symptoms, 15–19 moderately-severe depressive symptoms, and 20–27 severe depressive symptoms.

- *Anxiety*: The self-administered Hospital Anxiety and Depression Scale HADS-A subscale (27) is a 7-item questionnaire, validated in Spanish, and used in primary care (28–30). Items are scored from 0 to 3, with a score of 8 indicating possible and >10 probable anxiety with good specificity and predictive value (31).

- *Treatment burden*: Based on the self-administered Treatment Burden Questionnaire - TBQ (32). A 10-item version was validated in primary care of the UK in patients with multimorbidity (33). It uses a Likert scale that ranges from 0 (not difficult / does not apply) to 4 (extremely difficult) to assess the burden related to taking medication, self-care, medical appointments, and the need for organization. We will translate and adapt the MTB Questionnaire using the forward and back-translation procedure.

- *Health-related quality of life (HRQoL)*: We will assess this construct using the self-administered EQ-5D-5L (34) validated in Spanish and used in primary care (35). It enables the calculation of Quality-Adjusted Life Years (QALYs). The EQ-5D-5L descriptive system comprises five dimensions (mobility, personal care, daily activities, pain/discomfort, and anxiety/depression).

Explanatory and adjustment variables

- *Sociodemographic*: Age (years), gender, nationality, whether they live in Madrid or Canarias, marital status (married/partner, single, separated, divorced, widowed), number of living children, whether they have caregiving duties for parents (yes/no), educational level (incomplete primary studies, complete primary studies, secondary education, university studies or equivalent), and current occupation (i.e., unemployed, employed, self-employed, sick leave, another situation).

- *Morbidity*: Number and description of concomitant chronic diseases. This information will be collected by collaborating professionals coinciding with the baseline evaluation of each patient. An additional file of the O'Halloran list shows this in more detail (See Additional file 3) (36).

- *Treatment*: We will record the quantity and details of medications prescribed for long-term (i.e., at least three months), continuous use for each patient. This information will be meticulously collected by our team of collaborating HCPs at the time of each patient's baseline assessment, ensuring accurate and comprehensive medication data.

- *Use of resources*: Primary care (PC) visits, visits to the emergency department, visits to specialists, number of hospitalizations, lengths of stay.

- *Loss of productivity:* Self-administered questionnaire about work absences related to the illness.
- *Use of VCoP*: VCoP use data will be collected through the platform database.
- *Unintended consequences* of the interventions will be monitored along the duration of the study (37).

All the outcome measures will be collected online from a patient self-reported questionnaire that the research team will elaborate. VCoP use data will be collected through the platform database.

See table 2 for more details.

Timeline

The primary outcome of our study (PAM), will be evaluated over a period of 12 months, starting from baseline. To ensure a thorough understanding of the PAM's progression, we will also conduct additional assessments at 6 and 18 months. Secondary outcome measures will be collected before the start of the VCoP intervention and at 6, 12 and 18 months. This information is shown with more details in Figure 2.

Data monitoring

The data will be monitored by the research team throughout the research process. Special attention will be paid to their quality and their correct collection. Primary analyzes will be conducted following completion of the 6-, 12-, and 18-month assessment questionnaires.

Randomization and blinding

The STATA 17.0 software will generate a random sequence used by an investigator to allocate participants to different platform groups and notify them via email, after they have been

provided written consent. The intervention allocation will be blinded to participants, clinicians, and data analysts.

Statistical analysis

Sociodemographic and clinical baseline variables of both groups will be analyzed by descriptive methods according to the type of variable (mean [standard deviation (SD)], median [range], n [%]). The VCoP effect on the primary and secondary outcomes will be examined by means of repeated measures mixed linear models, with the intervention, time-point (0, 6, 12 and 18 months) and their interaction as fixed effects (along with other potential covariates), random intercepts for patients and clinicians, and unstructured covariance to account for within-subject correlations. We will also analyze the three-way interaction intervention × time × center, since usual care could vary between centers, leading to differential intervention effects. We expect to recruit enough clinicians to allow their inclusion in the model as a random intercept, but we will perform a sensitivity analysis as well as excluding this component. Between-group differences at each time-point will be compared by means of Wald's $\chi 2$ test. We will perform the analyses on an intention-to-treat basis (a sensitivity analysis on the per-protocol population will also be performed). Multiple imputation will be used for missing data, if applicable (Markov Chain Monte Carlo multivariate imputation algorithm, with 10 imputations per variable). Analyses will be carried out with the statistical software R V.4.0.2 (http://www.R-project.org/).

We will conduct a cost-effectiveness analysis of the VCoP over 18 months, comparing it to standard care with educational access for middle-aged patients with multimorbidity. This analysis will include both direct healthcare costs and indirect costs like productivity losses. Costs for each patient will be calculated using healthcare resources and the indirect costs will

be assessed based on productivity impacts. The study will also include the initial costs of developing and implementing the VCoP, and any costs incurred during the follow-up period.

The primary measure will be the cost per QALY gained. We will derive QALY estimates from the EQ-5D-5L questionnaire completed by patients at the study's start and each follow-up. The results will be presented as the incremental cost-effectiveness ratio (ICER), which compares cost and health outcomes differences between the VCoP and standard care. We will use robust statistical methods to ensure reliable ICER estimates and conduct sensitivity analyses to evaluate the effects of various factors on the results. The analysis will help determine whether the VCoP is a cost-effective option within our health system.

Sample size

To detect a mean difference of 4 points (SD = 10) in the PAM between the intervention and control groups, with individual randomization, 100 patients per group are required. This threshold of 4 points (SD = 10) was selected to capture clinically meaningful changes in patient activation (18). For this calculation, an alpha error of 0.05 and a power of 80% are assumed. This size is increased by the estimate of 20% loss, making a total of 240 patients.

Patient and public involvement

This protocol was developed without patient or public involvement. A group of middle-aged patients with multimorbidity will actively participate in a content-design previous stage using a co-creation methodology with virtual activities.

ETHICS AND DISSEMINATION

Informed consent (Additional file 4) will be obtained from each participant before randomization. The project has been approved by the local Ethics Committees of each participating Autonomous Community: Clinical Research Ethics Committee of Gregorio

Marañón University Hospital in Madrid (PI22/01124) and Nuestra Señora de Candelaria University Hospital in Santa Cruz de Tenerife (CHUNSC_2023_06) (Additional files 5 and 6). Patients will be personally informed by their physicians or nurses about the study and the possibility to participate during a programmed consultation. They will receive written information of the proposed research project, regarding its aims, the duration of their involvement, the expected benefits for them and the procedures involved in the participation. Recruiters will emphasize that enrollment in the study is voluntary, that participants can withdraw at any moment of the project, and that any decision they take in this respect will have no bearing on the medical care received. Once patients have signed the written informed consent, a researcher from the 'e-mpoderaT' team will contact them via phone and/or email to provide further information along with the necessary data (username and password) to login into the online platform. Additionally, recruiters will highlight that information generated by the study will be published, but no identification details will be divulged. Patients and healthcare professionals will be informed of whom to contact in case of any query, and research staff will be available to answer questions. We will prepare presentations to disseminate the study findings to healthcare stakeholders and patients, and at relevant national and international conferences. We aim to publish the results of the trial in peer-reviewed journals and try to grant public access to the full manuscripts.

TRIAL STATUS

The recruitment of patients in each region will start in January-February 2024. The estimated end date of the recruitment for this study is June 2024. This information is shown in more detail in Figure 3.

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DECLARATIONS

Contributors

VR, DK, JB, SGE, HVR, ADD, CM, MvdA, CO, LPP and AIGG contributed to the design of the study. AIGG and LPP are the guarantors. ACG and IGL wrote the first draft of the manuscript. VR, DK, ASA, JB, SGR, AC, PC, CCS, SDC, JGG, SGE, BGL, JV, CMG, CSF, PPC, EVR, PQC, ARP, MRL, ETB, ESG, BUA, HVR, ADD, AAS, AHY, ATC, YAP, CM, MvdA, VM, CO, LPP and AIGG contributed to the manuscript. The corresponding author attests that all listed authors meet the authorship criteria and that no others meeting the criteria have been omitted.

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Consent for publication

All authors read, approved the final manuscript and .gave their consent for publication.

Availability of data and materials

To maintain participants confidentiality, all information will be stored with anonymized identification code (ID code) numbers. All data will be stored on an electronic database management system located on a secure server with password-controlled access provided for research data collection. The Research Ethics Committees, the representatives of the Health Authority in matters of inspection and the personnel authorized by the Promoter, may only

access to check personal data, clinical study procedures and compliance with the rules of good clinical practice (always maintaining the confidentiality of information). Data will be available for any audit process.

Competing interests

The authors declare no conflict of interest.

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Word count

2724

Figure legend

Figure 1. Implementation strategies flow-chart

Figure 2. Schedule of enrolment, interventions, and assessments

Figure 3. Project timeline

Table 1. Implementation strategy.

INTERVENTION COMPONENTS	INTERVENTION GROUP "Virtual Community of Practice"	ACTIVE CONTROL "Self-administered education"
Provisioning and support methods	Provision of information Skills training Emotional support Proposal of objectives and action plans Training in self-monitoring of symptoms and monitoring of healthy behaviors Using reminders Social support by peers and professionals (key to the intervention)	Provision of information Using reminders
Type of encounters	Support sessions	Self-administered intervention
Support modality	Remote (web-based)	Remote (web-based)
Type of platform	Web platform compatible with mobile devices	Web platform compatible with mobile devices
Type of communication	Synchronous (webinar-type activities, virtual meetings) and asynchronous (web)	Asynchronous (web)
Recipients	In a group	Individual
Type of providers interacting with patients	Professionals in primary and specialized care medicine, nursing, psychology.	There is no interaction with patients.
Setting	Primary care patients	Primary care patients
Content topics (examples)	Healthy life habits Clinical management of pathologies (symptom management, pathology adherence) Emotional and stress management Social management (job compatibility, social roles)	Healthy life habits Clinical management of pathologies (symptom management, pathology adherence) Emotional and stress management Social management (job compatibility, social roles)
Outcomes measured	Activation, anxiety and depression, disease burden, quality of life, resource use	Activation, anxiety and depression, disease burden, quality of life, resource use
Type of patients	Middle-aged people with multimorbidity	Middle-aged people with multimorbidity
Content development	Co-designed. A multidisciplinary group of professionals prepares and reviews the contents. New contents according to the dynamics of participation and the needs of the group that participates in the community	Co-designed. A multidisciplinary group of professionals prepares and reviews the contents.

Source: Based on TIDieR guide (https://doi.org/10.1136/bmj.g1687) and Taxonomy of self-management interventions for chronic conditions (16).

Table 2. Trial outcomes

VARIABLES	NAME	TYPE OF VARIABLE	MEASURES
Primary	PAM (Patient Activation Measure)	Ordinal qualitative	Likert scale: 0-100, where 100 indicates highest level of activation
Secondary	PHQ-9 (Patient Health Questionnaire)	Ordinal qualitative	Likert scale: Depression intervals: 0-4, 5-9, 10-14, 15-19, 20-27
	HADS-A (Hospital Anxiety and Depression Scale: Subscale of Anxiety)	Ordinal qualitative	Likert scale: Scored each item 0-3. >8 indicates possible cases
	TBQ (Treatment Burden Questionnaire)	Ordinal qualitative	Likert scale: 0-20, where 20 indicates significant problem
	HRQoL (Health Related Quality of Life)	Ordinal qualitative	Likert scale: Never-very often
Sociodemographic	Age	Discrete quantitative	years
	Sex (Gender)	Categorical Qualitative	4 categories: 1-Male, 2- Female, 3-Other, 4- Refused to answer
	Nationality	Nominal	Open question
	Autonomous Community of residence	Categorical Qualitative	2 categories: 1-Madrid, 2-Canary Islands
	Marital status	Categorical Qualitative	5 categories: 1-Married/partner, 2-single, 3-separated, 4-divorced, 5-widowed
	Have children	Dichotomous qualitative	Yes/no
	Number of children	Discrete	Open question (number/units)
	Caring parents	Dichotomous qualitative	Yes/no

VARIABLES	NAME	TYPE OF VARIABLE	MEASURES
	Educational level	Categorical Qualitative	4 categories: 1-Incomplete primary studies, 2-complete primary studies, 3-secondary education, 4-university studies or equivalent
	Current occupation	Nominal	Open question
Multimorbidity	Number and description of concomitant chronic diseases	Discrete / Nominal	O'Halloran list
Treatment	Number and description of chronic treatments	Discrete / Nominal	Open question (number of treatments in electronic medical record)

498

Figure 1.- Implementation strategies flow-chart

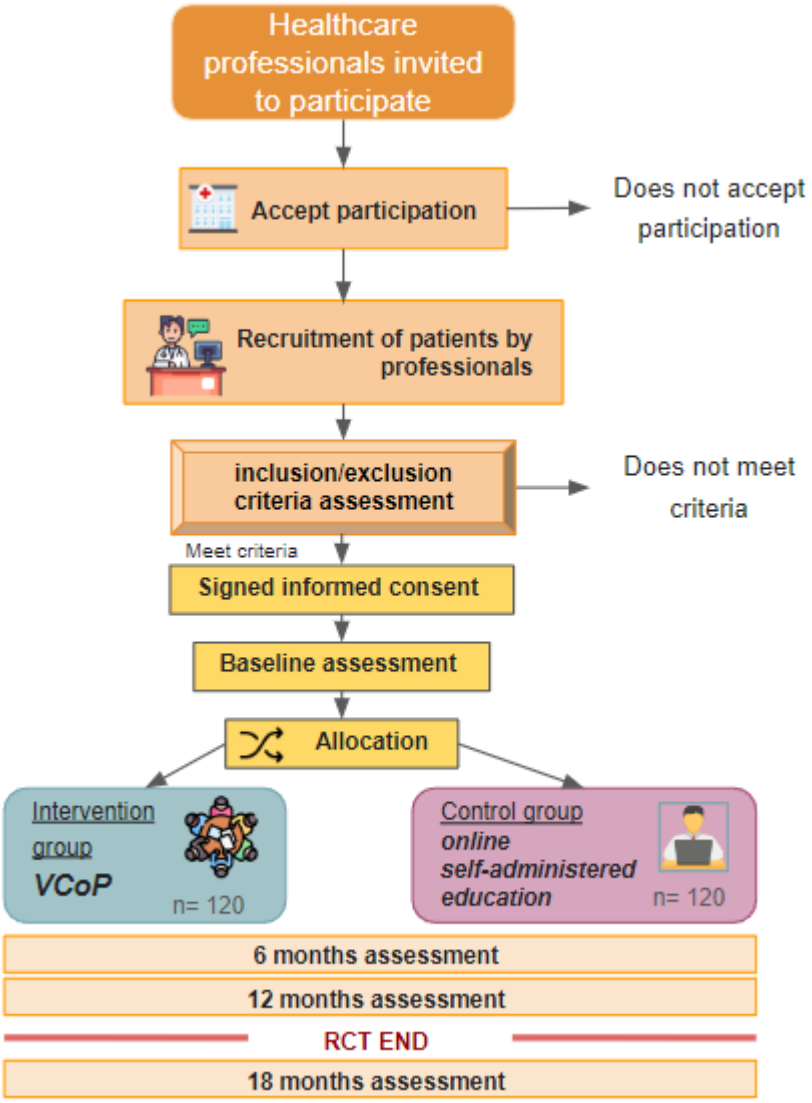


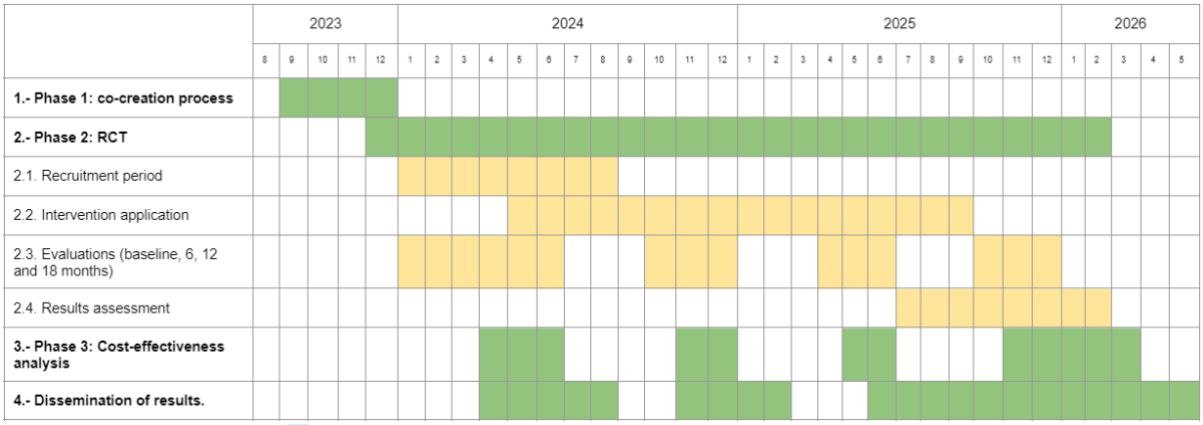
Figure 2. Schedule of enrolment, interventions, and assessments

	Study period					
		Preallocation		Postallocation		Close-out
	Phase 1	Enrolment	Baseline	6 months	12 months	18 months
Co-creation process	X					
Eligibility creen	X*	X				
Informed consent	X*	X				
Interventions						
VCoP						
Usual Care						
Assessments						
Sociodemographic variables			X			
Morbidity			X			
Treatment			X			
PAM			X	X	X	X
PHQ-9			X	X	X	X
HADS-A			X	X	X	X
TBQ			X	X	X	X
E5-5D-5L			X	X	X	X
Use of resources				X	X	X
Use of VCoP				X	X	
Unintended consequences				X	X	X

*The eligibility screen and informed consent of the co-creation phase are like the RCT phase.

HADS, Hospital Anxiety and Depression Scale; PAM, Patient Activation Measure; PHQ-9, Patient Health Questionnaire; TBQ, Treatment Burden Questionnaire; SPIRIT, Standard Protocol Items: Recommendations for Interventional Trials; VCoP, Virtual Community of Practice.

Figure 3. Project timeline



SPIRIT | CONSORT OUTCOMES
Reporting Guidelines for Trial Outcomes

Additional file 1 - SPIRIT-Outcomes 2022 Checklist (for combined completion of SPIRIT 2013 and SPIRIT-Outcomes 2022 items)

Section	Item	SPIRIT 2013 Item	SPIRIT-Outcomes 2022 item	Location Reported
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 ofintended registry	-	4
	2b	All items from the World HealthOrganization Trial RegistrationData Set	-	N/A
Protocol version	3	Date and version identifier	-	Left header
Funding	4	Sources and types of financial, material, and other support	-	4
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	-	1-2
	5b	Name and contact information for the trial sponsor	-	2
	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	-	N/A
	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 monitoringcommittee)	-	1-2
Introduction				
Background and rationale	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	-	5-6
	6b	Explanation for choice ofcomparators	-	5-6
Objectives	7	Specific objectives or hypotheses	-	6

Section	Item No.	SPIRIT 2013 Item	SPIRIT-Outcomes 2022 item	Location Reported
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)	-	6
Methods: Participants, interventions, and outcomes				
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	-	7
Eligibility criteria	10	Inclusion and exclusion criteria forparticipants. If applicable, eligibility criteria for study centres and individuals who will perform. the interventions (eg, surgeons, psychotherapists)	-	7
Interventions	11a	Interventions for each group withsufficient detail to allow replication, including how and when they will be administered. (for specific guidance see TIDieR checklist and guide)	-	9 (See Table 1)
	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)	-	N/A
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	-	N/A
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	-	9 (See Table 1)
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 theclinical relevance of chosen efficacy and harm outcomes is strongly recommended	-	10-12 (See Table 2)

Section	Item No.	SPIRIT 2013 Item	SPIRIT-Outcomes 2022 item	Location Reported
	12.1		Provide a rationale for the selection of the domain for the trial's primary outcome	10
	12.2		If the analysis metric for the primary outcome represents within-participant change, define, and justify the minimal important change in individuals	14
	12.3		If the outcome data collected are continuous but will be analyzed as categorical (method of aggregation), specify the cutoff values to be used	N/A
	12.4		If outcome assessments will be performed at several time points after randomization, state the time points that will be used for analysis	12 (See Figure 2)
	12.5		If a composite outcome is used, define all individual components of the composite outcome	N/A
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 Figure)	-	12 (See Figure 2)
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	-	14
	14.1		Define and justify the target difference between treatment groups.(eg, the minimal important difference)	14
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	-	8
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 enroll participants or assign interventions	-	13

Section	Item No.	SPIRIT 2013 Item	SPIRIT-Outcomes 2022 item	Location Reported
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	-	13
Implementation	16c	Who will generate the allocation sequence, who will enroll participants, and who will assign participants to interventions	-	8, 13
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	-	13
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	-	N/A
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	-	10-12 (See Figure 2)
	18a.1		Describe what is known about the responsiveness of the study instruments in a population similar to the study sample	10-12
	18a.2		Describe who will assess the outcome (eg, nurse, parent)	13
	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	-	N/A

Section	Item No.	SPIRIT 2013 Item	SPIRIT-Outcomes 2022 item	Location Reported
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	-	18
Statistical methods	20a	Statistical methods for analyzing primary and secondary outcomes.Reference to where other details of the statistical analysis plan can be found, if not in the protocol	-	13
	20a.1		Describe any planned methods to account for multiplicity in the analysis or interpretation of the primary and secondary outcomes (eg, coprimary outcomes, same outcome assessed at multiple time points, or subgroup analyses of an outcome)	13
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	-	13
	20c	Definition of analysis population relating to protocol non- adherence (eg, as randomized analysis), and any statistical methods to handle missing data (eg, multiple imputation)	-	13
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 detailsabout its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	-	12
	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 thetrial	-	13
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	-	12

Section	Item No.	SPIRIT 2013 Item	SPIRIT-Outcomes 2022 item	Location Reported
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	-	18
Ethics and dissemination				
Research ethics approval	24	Plans for seeking research ethicscommittee/institutional review board (REC/IRB) approval	-	17
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	-	17
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorized surrogates, and how (see Item 32)	-	17
	26b	Additional consent provisions forcollection and use of participant data and biological specimens in ancillary studies, if applicable	-	N/A
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
Declaration of interests	28	Financial and other competing interests for principal investigatorsfor the overall trial and each study site	-	18
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such accessfor investigators	-	18
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	-	N/A
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	-	17
	31b	Authorship eligibility guidelinesand any intended use of professional writers	-	N/A

Section	Item No.	SPIRIT 2013 Item	SPIRIT-Outcomes 2022 item	Location Reported
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	-	17
Appendices				
Informed consent materials	32	Model consent form and other related documentation given to participants and authorized surrogates	-	See Additional File 3
Biological specimens	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	-	N/A

[a]It is strongly recommended that this checklist be read in conjunction with the SPIRIT (Standard Protocol Items: Recommendatio ns for Interventional Trials) Statement paper for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license and is reproduced with permission.
[b]Indicates page numbers and/or manuscript location: to be completed by authors.

Source: Butcher NJ, Monsour A, Mew EJ, et al. Guidelines for reporting outcomes in trial protocols: the SPIRIT-Outcomes 2022extension. JAMA. Published online December 13, 2022. doi:10.1001/jama.2022.21243

Additional file 2 - Questionnaire on computer and internet use

QUESTIONNAIRE ON COMPUTER AND INTERNET USE

(This questionnaire will be completed by the research team during the first telephone contact with the patient).

Patient ID:
Autonomous Community:
Referral health center/hospital:

Please answer the following questions about computer and internet use:

1. What type of device do you own? (Check all that apply):
   · Computer
   · Tablet
   · Laptop
   · Smartphone

   * *To meet the study requirements, patients must have at least one device.*

2. Do you have Internet access on your devices?
   · Yes
   · No

   * *To meet the study requirements, only patients that answer YES could participate.*

3. How often do you use the Internet (including email)?
   · Never
   · Less than once a month
   · Once a month
   · Once or twice a week
   · Everyday

   * *To meet the study requirements, patients who check ONE OF THE FIRST TWO BOXES will not be able to participate.*

4. When you are online, which of the following activities do you do? (check all that apply):
   · I check the email
   · Web surfing / Searching information
   · Shopping / User accounts payment
   · I play video games
   · I download or listen to music
   · I watch videos or movies
   · I use social networks (e.g. Facebook, Instagram, Twitter, Snapchat, Telegram,...)
   · I send instant messages (e.g. Skype, WhatsApp, Facebook Messenger, Telegram..)
   · I read press news

· I take courses or distance studies
· Use of different Apps

** To meet the study requirements, patients must check AT LEAST 3 BOXES to participate.*

Additional file 3 - O'Halloran list

CHAP	ICPC-2 RUBRIC	DESCRIPTION	ICPC-2 PLUS CODE	DESCRIPTION
A	*A04*	*Weakness/Tiredness general*	*029*	*Chronic fatigue syndrome*
			031	*Myalgic encephalomyelitis*
			030	*Post viral fatigue syndrome*
			028	*Post viral syndrome*
	A70	Tuberculosis		
	A79	Malignancy, NOS		
	A90	Congenital anomaly NOS/multiple		
B	B72	Hodgkin's disease/lymphoma		
	B73	Leukaemia		
	B74	Malignant neoplasm blood other		
	B75	*Benign/unspecified neoplasm blood*	*008*	*Myelodysplastic syndrome*
			004	*Polycythaemia rubra vera*
	B78	Hereditary haemolytic anaemia		
	B81	Anaemia, Vit B12/folate deficiency		
	B82	Anaemia, other/unspecified		
	B83	Purpura/coagulation defects		
	B90	HIV infection/AIDS		
D	*D72*	*Viral hepatitis*	*003*	*Hepatitis B*
			008	*Hepatitis C*
			009	*Hepatitis D*
	D74	Malignant neoplasm stomach		
	D75	Malignant neoplasm colon/rectum		
	D76	Malignant neoplasm pancreas		

CHAP	ICPC-2 RUBRIC	DESCRIPTION	ICPC-2 PLUS CODE	DESCRIPTION
	D77	Malignant neoplasm digestive other/NOS		
	D81	*Congenital anomaly digestive system*	*011*	*Atresia;biliary*
			005	*Cleft;palate/lip*
			007	*Disease;Hirschsprungs*
			002	*Harelip*
			001	*Megacolon;congenital*
	D84	Congenital anomaly digestive system		
	D85	Duodenal ulcer		
	D86	Peptic ulcer other		
	D92	Diverticular disease		
	D93	Irritable bowel syndrome		
	D94	Chronic enteritis/ulcerative colitis		
	D97	Liver disease NOS		
	D98	Cholecystitis/cholelithiasis		
	D99	*Disease digestive system, other*	*029*	*Blind loop syndrome*
			032	*Insufficiency;pancreatic*
			017	*Insufficiency;vascul;mesentery*
			013	*Gluten sensitivity*
			015	*Intolerance;fat*
			012	*Intolerance;gluten*
			054	*Intolerance;lactose*
			028	*Malabsorption syndrome*
			043	*Pancreatitis*
			036	*Pyloric stenosis;acquired*
			024	*Sprue*
			055	*Stenosis;anal*

CHAP	ICPC-2 RUBRIC	DESCRIPTION	ICPC-2 PLUS CODE	DESCRIPTION
			025	*Stenosis;sigmoid colon*
			016	*Thrombosis;mesenteric*
F	*F74*	*Neoplasm of eye/adnexa*	*003*	*Carcinoma;eye*
			002	*Neoplasm malig;eye*
	F83	Retinopathy		
	F84	Macular degeneration		
	F92	Cataract		
	F93	Glaucoma		
	F94	Blindness		
H	*H75*	*Neoplasm of ear*	*003*	*Carcinoma;ear*
			002	*Neoplasm malig;ear*
	H82	Vertiginous syndrome		
	H84	Presbyacusis		
	H86	Deafness		
K	*K71*	*Rheumatic fever/heart disease*	*010*	*Carditis;rheumatic;chronic*
			012	*Myocarditis;rheumatic;chronic*
			015	*Stenosis;arterial;rheumatic*
			005	*Stenosis;mitral;rheumatic*
	K72	*Neoplasm, cardiovascular*	*003*	*Carcinoma;cardiovascular*
			002	*Neoplasm malig;cardiovascular*
	K73	Congenital anomaly, cardiovascular		
	K74	Ischaemic heart disease with angina		
	K75	Acute myocardial infarction		
	K76	Ischaemic heart disease without angina		
	K77	Heart failure		

CHAP	ICPC-2 RUBRIC	DESCRIPTION	ICPC-2 PLUS CODE	DESCRIPTION
	K78	Atrial fibrillation/flutter		
	K79	Paroxysmal tachycardia		
	K80	Cardiac arrhythmia NOS		
	K81	Heart/arterial murmur NOS		
	K82	Pulmonary heart disease		
	K83	Heart valve disease NOS		
	K84	Heart disease, other		
	K86	Hypertension, uncomplicated		
	K87	Hypertension, complicated		
	K88	Postural hypotension		
	K89	Transient cerebral ischaemia		
	K90	Stroke/cerebrovascular accident		
	K91	Cerebrovascular disease		
	K92	Atherosclerosis/peripheral vascular disease		
	K93	Pulmonary embolism		
	K94	Phlebitis/thrombophlebitis		
	K95	Varicose veins of leg		
L	L71	Malignant neoplasm, musculoskeletal		
	L82	*Congenital anomaly, musculoskeletal*	*001*	*Achondroplastic dwarf*
			003	*Clubfoot*
			015	*Curvature of spine;congenital*
			025	*Deformity;foot;congenital*
			024	*Dislocation;hip;congenital*
			013	*Ehlers Danlos syndrome*
			021	*Kyphoscoliosis;congenital*

CHAP	ICPC-2 RUBRIC	DESCRIPTION	ICPC-2 PLUS CODE	DESCRIPTION
			019	*Kyphosis;congenital*
			007	*Lordosis;congenital*
			018	*Osteogenesis imperfecta*
			027	*Plagiocephaly*
			012	*Scoliosis;congenital*
			014	*Talipes*
	L83	Neck syndrome		
	L84	Back syndrome without radiating pain		
	L85	Acquired deformity of spine		
	L86	Back syndrome with radiating pain		
	L88	Rheumatoid/seropositive arthritis		
	L89	Osteoarthritis of hip		
	L90	Osteoarthritis of knee		
	L91	Osteoarthritis, other		
	L92	Shoulder syndrome		
	L93	Tennis elbow		
	L95	Osteoporosis		
	L99	*Musculoskeletal disease, other*	*047*	*Arthropathy;Behcets syndrome*
			087	*Arthropathy;Reiters disease*
			088	*Chondromalacia;patella*
			013	*Disease;Pagets (bone)*
			093	*Dystrophy;muscular*
			056	*Lupus erythematosus*
			025	*Osteitis*
			026	*Osteitis deformans*
			060	*Polymyositis*

CHAP	ICPC-2 RUBRIC	DESCRIPTION	ICPC-2 PLUS CODE	DESCRIPTION
			071	*Progressive system sclerosis*
			075	*Reiters syndrome*
			078	*Repetitive Strain Injury*
			069	*Scleroderma;diffuse*
			070	*Scleroderma;localised*
			028	*Scleroderma;progressive*
			033	*Sjorgens syndrome*
			065	*Systemic lupus erythematosus*
N	N73	Neurological infection, other		
	N74	Malignant neoplasm nervous system		
	N75	Benign neoplasm nervous system		
	N76	Neoplasm nervous system, unspecified		
	N85	Congenital anomaly neurological		
	N86	Multiple sclerosis		
	N87	Parkinsonism		
	N88	Epilepsy		
	N89	Migraine		
	N90	Cluster headache		
	N92	Trigeminal neuralgia		
	N93	Carpal tunnel syndrome		
	N94	Peripheral neuritis/neuropathy		
	N99	*Neurological disease, other*	*025*	*Arachnoiditis*
			005	*Atrophy;cerebral*
			004	*Chorea;Huntingtons*
			027	*Degeneration;cerebral*
			010	*Disease;motor neuron*

CHAP	ICPC-2 RUBRIC	DESCRIPTION	ICPC-2 PLUS CODE	DESCRIPTION
			042	*Encephalopathy*
			043	*Encephalopathy;Wernickes*
			011	*Myasthenia Gravis*
			003	*Palsy;cerebral*
			022	*Palsy;infantile spastic*
			040	*Palsy;spastic*
			017	*Paralysis;infantile spastic*
			018	*Paraplegia*
			020	*Quadriplegia*
			030	*Syringomyelia*
P	P15	Chronic alcohol abuse		
	P70	Dementia		
	P71	Organic psychosis, other		
	P72	Schizophrenia		
	P73	Affective psychosis		
	P74	Anxiety disorder/anxiety state		
	P75	Somatisation disorder		
	P76	Depressive disorder		
	P78	Neuraesthenia, surmenage		
	P79	Phobia/compulsive disorder		
	P80	Personality disorder		
	P81	Hyperkinetic disorder		
	P82	Post-traumatic stress disorder		
	P85	Mental retardation		
	P86	Anorexia nervosa/bulimia		
	P98	Psychosis NOS/other		

CHAP	ICPC-2 RUBRIC	DESCRIPTION	ICPC-2 PLUS CODE	DESCRIPTION
	P99	*Psychological disorders, other*	*005*	*Autism*
			006	*Autism;child*
R	R84	Malignant neoplasm bronchus, lung		
	R85	Malignant neoplasm respiratory, other		
	R90	Hypertrophy tonsils/adenoids		
	R95	Chronic obstructive pulmonary disease		
	R96	Asthma		
	R99	*Respiratory disease, other*	*015*	*Asbestosis*
			018	*Bronchiectasis*
			004	*Failure;respiratory*
			009	*Farmers lung*
			019	*Fibrosing alveolitis*
			010	*Fibrosis;pulmonary*
			012	*Pneumoconiosis*
			020	*Pneumonia;interstitial*
S	S77	Malignant neoplasm of skin		
	S86	Dermatitis, seborrhoeic		
	S87	Dermatitis/atopic eczema		
	S91	Psoriasis		
	S96	*Acne*	*007*	*Acne*
			003	*Acne;conglobulate (cystic)*
			002	*Acne;vulgaris*
	S99	*Skin disease, other*	*001*	*Acne;rosacea*
			003	*Dermatitis;herpetiformis*
			034	*Discoid lupus erythematosus*
			042	*Lichen sclerosus*

CHAP	ICPC-2 RUBRIC	DESCRIPTION	ICPC-2 PLUS CODE	DESCRIPTION
			031	*Necrobiosis lipoidica diabetic*
			018	*Pemphigus*
			021	*Rhinophyma*
T	T71	Malignant neoplasm thyroid		
	T73	*Neoplasm endocrine other/uncertain*	*001*	*Carcinoma;endocrine*
			002	*Neoplasm malig;endocrine*
	T80	*Congenital anomaly endocrine/metabolic*	*007*	*Cretinism*
			001	*Disease;Hurlers*
			002	*Dwarfism*
			005	*Pseudohypoparathyroidism*
	T81	Goitre		
	T82	Obesity		
	T83	Overweight		
	T85	Hyperthyroidism/thyrotoxicosis		
	T86	Hypothyroidism/myxoedema		
	T89	Diabetes, insulin dependent		
	T90	Diabetes, non-insulin dependent		
	T92	Gout		
	T93	Lipid disorder		
	T99	*Endocrine/metabolic/nutritional disease, other*	*001*	*Acromegaly*
			006	*Amyloidosis*
			028	*Cushings syndrome*
			053	*Cystic fibrosis*
			011	*Diabetes insipidus*
			002	*Disease;Addisons*

CHAP	ICPC-2 RUBRIC	DESCRIPTION	ICPC-2 PLUS CODE	DESCRIPTION
			064	*Disease;fibrocystic*
			013	*Disease;Gilberts*
			018	*Disease;Hashimotos*
			046	*Disease;Wilsons*
			035	*Haemochromatosis*
			073	*Homocystinuria*
			036	*Hyperaldosteronism*
			037	*Hyperparathyroidim*
			069	*Hyperprolactinaema*
			030	*Hypoparathyroidism*
			023	*Phenylketonuria*
			043	*Polycystic ovary syndrome*
			026	*Porphyria*
			040	*Stein Leventhal syndrome*
			041	*Thyroiditis*
U	U75	Malignant neoplasm kidney		
	U76	Malignant neoplasm bladder		
	U77	Malignant neoplasm, urinary, other		
	U88	Glomerulonephritis/nephrosis		
	U99	*Urinary disease, other*	*019*	*Diverticulitis;bladder*
			023	*Failure;renal;chronic*
			022	*Insufficiency;renal*
			006	*Necrosis;renal*
			024	*Necrosis;renal;papillary*
			013	*Reflux;ureteric*
			028	*Stenosis;artery;renal*

CHAP	ICPC-2 RUBRIC	DESCRIPTION	ICPC-2 PLUS CODE	DESCRIPTION
			017	*Stenosis;urethral*
W	W15	Infertility/subfertility		
	W72	Malignant neoplasm related to fertility		
X	X74	Pelvic inflammatory disease		
	X75	Malignant neoplasm cervix		
	X76	Malignant neoplasm breast female		
	X77	Malignant neoplasm genital female other		
	X99	*Genital disease, other*	*016*	*Endometriosis*
			009	*Fistula;vaginal*
Y	Y77	Malignant neoplasm prostate		
	Y78	Malignant neoplasm male genital, other		
	Y85	Benign prostatic hypertrophy		

N.B. Italics indicate that the ICPC-2 rubric is chronic only at the ICPC-2 PLUS level. Conditions listed in the 'ICPC-2 PLUS Code' column are those within the rubric which have been labelled as chronic using the extended terminology of ICPC-2 PLUS.

Source: O'Halloran J, Miller GC, Britt H. Defining chronic conditions for primary care with ICPC-2. Family Practice [Internet]. 2004 Aug 1;21(4):381–6.

Additional file 4 - Informed consent

Patient information sheet

Clinical trial

INTRODUCTION

Dear Sir or Madam,

We would like to inform you that we are implementing the clinical trial entitled "Effectiveness and cost-effectiveness of a virtual Community of Practice (CdPV web application) for improving the empowerment of middle-aged individuals with multimorbidity: RCT".

This is a multicenter project involving Madrid: PI22/01124, the project coordinator, and the Canary Islands: PI22/00691.

This study has been approved by the Ethics Committees for Clinical Research of the participating centers in accordance with current legislation, Organic Law 3/2018, of December 5, on the Protection of Personal Data and the Guarantee of Digital Rights, and the application of Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016. Here you will find the correct and sufficient information to evaluate and decide whether or not you want to participate in this study. To do so, please read this information sheet carefully, and we will clarify any doubts that may arise after the explanation. Furthermore, you may consult with anyone you deem appropriate.

Voluntary participation

You should be aware that your participation in this study is voluntary, and you have the right to choose not to participate or change your decision and withdraw your consent at any time. Your decision will not affect your relationship with your doctor, nor will it cause any harm to your treatment.

Who are the researchers?

The research team is a multidisciplinary group of professionals, including medical doctors, psychologists, statisticians, healthcare service evaluators, general practitioners, nurses, and cardiologists. The team members are affiliated with the following institutions: Avedis Donabedian Foundation, Primary Care Management, and the Directorate General of Research, Teaching, and Innovation of the Ministry of Health of the Community of Madrid, as well as the Service for the Evaluation of the Canary Islands Health Service (SESCS).

STUDY DESCRIPTION

Why is this study being conducted?

The purpose of this study is to evaluate the effectiveness of a virtual Community of Practice (VCoP) for middle-aged individuals with multiple chronic diseases. We aim to improve their knowledge, skills, and self-confidence in managing their own health. This will be measured using the specific Patient Activation Measure (PAM) questionnaire, which assesses activation levels in individuals with chronic diseases, at 12-months, comparing it with the active control group.

Who can participate?

If you are between 30 and 60 years old, have been diagnosed with two or more chronic diseases, and have internet access at home and/or a smartphone, you are eligible to participate.

Study procedure:

There will be two study groups: the Intervention Group (GI) and the Control Group (GC). Participants will be randomly assigned to one of these groups. If you decide to participate in the study, you could be placed in either group.

If you choose to participate, what does your involvement entail?

The study will last for 18 months. At the beginning of the study and at 6, 12, and 18 months, participants will complete online questionnaires. These questionnaires will assess various aspects related to each participant's level of activation in health-related decisions (PAM questionnaire), depression using the self-administered Patient Health Questionnaire-9 (PHQ-9), anxiety using the self-administered Hospital Anxiety and Depression Scale - Anxiety Subscale (HADS-A), treatment burden using the self-administered Treatment Burden Questionnaire (TBQ), and health-related quality of life using the self-administered E5-5D-5L questionnaire (EuroQol group). Completing these questionnaires will take approximately 30 minutes.

During the baseline visit, sociodemographic variables and other variables related to your chronic diseases and treatment will be collected. If necessary, access to your medical history may be granted to verify this information.

If you are randomly assigned to the IG, you will be offered the opportunity to participate for 18 months in a Virtual Community of Practice (VCoP) based on a web 2.0 platform. A registration link will be provided to you via email to initiate your voluntary participation.

In the Virtual Community of Practice (VCoP), you will have access to leisure and educational activities based on strategies that facilitate learning, as well as the exchange of knowledge and experiences among participants and a multidisciplinary team of professionals. Various topics related to health competencies, self-efficacy techniques, lifestyle, acceptance of chronic illness, and shared decision-making will be addressed.

If you are randomly assigned to the CG, you will continue to receive the standard care and attention provided in regular clinical practice. Additionally, you will be offered the same educational content as the intervention group but self-administered.

Benefits and risk of participating in this study.

There are no anticipated physical or psychological risks associated with participating in this study. The main benefit for participants with multiple chronic diseases is the opportunity to improve their knowledge, skills, and self-confidence in managing their own health and healthcare.

Confidentiality

The processing, communication, and transfer of personal data of all participating individuals will comply with the provisions of Organic Law 3/2018, of December 5, on the Protection of Personal Data and Guarantee of Digital Rights, and the application of Regulation (EU) 2016/679 of the European Parliament and of the Council of April 27, 2016, on the Protection of Personal Data (GDPR). It is important that you are aware of the following information:

In addition to the rights, you are already familiar with (access, modification, objection, and cancellation of data), you now also have the right to limit the processing of incorrect data, request a copy of the data you have provided for the study, or have them transferred to a third party (data portability). Similarly, you have the right to withdraw your consent for data processing; however, such withdrawal may result in your discontinuation of participation in the trial. To exercise your rights, please contact the principal investigator of the study. Please note that data cannot be deleted even if you discontinue participation in the trial or withdraw your consent for data processing, to ensure the validity of the research and comply with legal obligations and medication authorization requirements. You also have the right to file a complaint with the Data Protection Agency if you are not satisfied.

Altogether, the Center, the Sponsor, and the Investigator are each responsible for your data processing and are committed to comply with current data protection regulations. The data collected for the study will be identified using a code, so that no information

that can identify you is included. Only your study doctor/collaborators will be able to link this data to you and your medical history. Therefore, your identity will not be disclosed to anyone else unless required by health authorities or in cases of medical emergency. The Research Ethics Committees, representatives of the Health Authority responsible for inspection, and authorized personnel from the Sponsor may access personal data to verify the study procedures and compliance with good clinical practice standards (always maintaining the confidentiality of the information).

The Investigator and the Sponsor are obligated to retain the data collected for the study for at least 25 years after its completion. Afterwards, your personal information will only be retained by the healthcare center for your health care purposes and by the Sponsor for other scientific research purposes if you have provided consent for such retention, and if allowed by law and applicable ethical requirements.

Additional information

As required by law, you will need to sign and date the informed consent document to participate.

Project coordinator. Principal investigator. (Madrid):

Ana Isabel González González,

Innovation and International Projects Unit.

Subdirección General de Investigación, Docencia e Innovación. Consejería de Sanidad de la Comunidad de Madrid.

contact: aisabel.gonzalezg@salud.madrid.org

Principal investigator (CANARIAS):

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

Contact: lperperr@gobiernodecanarias.org

Informed consent for patients

(name and surname) declares:

.....

That I have read the Patient information sheet.

That I could make any questions regarding the study

That I have enough information about the study

I received this information from:

.....

I understand that my participation is volunteer, and I can withdraw it:

1. Whenever I want.
2. I don't have to give any explanations.
3. Without any repercussions for my healthcare.

- I freely give my consent to participate in the study and authorize the access and use of my data under the conditions detailed in the information sheet.

Name of the participant:

Date: Signature:

Investigator name:

Date: Signature:

DICTAMEN DEL COMITÉ de ÉTICA DE LA INVESTIGACIÓN con MEDICAMENTOS

D. Roberto Collado Borrell, Secretario Técnico del **COMITÉ de ÉTICA DE LA INVESTIGACIÓN con MEDICAMENTOS HOSPITAL GENERAL UNIVERSITARIO GREGORIO MARAÑÓN**

CERTIFICA

Que se ha evaluado la propuesta del promotor referida al estudio observacional:

Código PI22/01124
TÍTULO: "Efectividad y coste-efectividad de una Comunidad de Práctica virtual (CdPV aplicación web) para la mejora del empoderamiento de personas de mediana edad con multimorbilidad: ECA"
Protocolo versión 2. 29 de mayo de 2023. **Hoja de Información al paciente y Consentimiento Informado Fase Ensayo Clínico** versión 3. 7 de junio de 2023. **Hoja de Información al paciente y Consentimiento Informado Fase Co-Diseño** versión 1. 20 de marzo de 2023.
Promotor: Investigador

- El estudio se plantea siguiendo los requisitos legalmente establecidos, y su realización es pertinente.
- Se cumplen los requisitos necesarios de idoneidad del protocolo en relación con los objetivos del estudio y están justificados los riesgos y molestias previsibles para el sujeto.
- Es adecuado el procedimiento para obtener el consentimiento informado
- El alcance de las compensaciones económicas previstas no interfiere con el respeto a los postulados éticos.
- La capacidad del investigador y sus colaboradores, y las instalaciones y medios disponibles, tal y como ha sido informado, son apropiados para llevar a cabo el estudio.

Este CEIm actuando como comité evaluador, emite **dictamen favorable** y acepta que dicho estudio sea realizado en los centros siguientes por los investigadores principales que se relacionan a continuación:

Dra. Ana Isabel González González / Unidad de Innovación y Proyectos Internacionales - Consejería de Sanidad de la Comunidad de Madrid

Y HACE CONSTAR QUE:

1º En la reunión celebrada el día **05 de junio de 2023**, **acta 11/2023** se decidió emitir el informe correspondiente al estudio de referencia.
2º En dicha reunión se cumplieron los requisitos establecidos en la legislación vigente -Real Decreto 1090/2015 y Decreto 39/94 de la Comunidad de Madrid- para que la decisión del citado CEIm sea válida.
3º El CEIm, tanto en su composición, como en los PNT cumple con las normas de BPC (CPMP/ ICH/ 135/95)
4º La composición actual del CEIm es la siguiente:

D. ANDRÉS JESÚS MUÑOZ MARTÍN (Oncología Médica - Presidente)
Dª. MARÍA LUISA NAVARRO GÓMEZ (Pediatría - Vicepresidenta)
D. ROBERTO COLLADO BORRELL (Farmacia Hospitalaria – Secretario Técnico)
D. JUAN ANTONIO ANDUEZA LILLO (Medicina Interna)
Dª. BEATRIZ AUDIBERT AMOROTO (Licenciada en Derecho)
Dª. MARÍA LUISA BAEZA OCHOA DE OCÁRIZ (Alergología)
Dª. PILAR AITANA CALVO FERRÁNDIZ (Farmacología Clínica)
Dª. ISABEL CASTREJÓN FERNÁNDEZ (Reumatología)
Dª MARÍA DEL CARMEN DE LA CRUZ ARGUEDAS (Unidad de Apoyo a la Investigación)
D. VICENTE DE LAS PEÑAS GIL (Psicología Clínica)
D. JAVIER DE MIGUEL DÍEZ (Neumología)
Dª. PATRICIA FONT LÓPEZ (Hematología y Hemoterapia)
Dª. ISABEL GÓMEZ VALBUENA (Farmacia de Atención Primaria)
D. PABLO GONZÁLEZ NAVARRO (Bioestad´sitica)
Dª. MARÍA DEL CARMEN HERAS ESCOBAR (Enfermería)
Dª. LUIS IBÁÑEZ SAMANIEGO (Digestivo)
Dª. ANA MARÍA IGLESIAS MOHEDANO (Neurología)
D. LUIS ANDRÉS LÓPEZ FERNÁNDEZ (Biología)
Dª. ANA ESTHER LÓPEZ PÉREZ (Anestesiología y Reanimación)
D. ANTONIO MUIÑO MIGUEZ (Medicina Interna)
Dª. SARA PÉREZ RAMÍREZ (Oncología)
D. JOSÉ LUIS REVUELTA HERRERO (Farmacia Hospitalaria)
D. EDUARDO ZATARAÍN NICOLÁS (Cardiología)

Lo que firmo en Madrid, a 07 de junio de 2023

Fdo.: Dr. Roberto Collado Borrell

C/ Dr. Esquerdo 46, Pabellón de Gobierno, Primera Planta, 28007 Madrid
ceim.hgugm@salud.madrid.org Tlf. 91 586 7007/91 426 9378

Servicio Canario de la Salud

Gobierno de Canarias

El estudio de investigación titulado: "**Efectividad y coste-efectividad de una Comunidad de Práctica Virtual (CdPV aplicación web) para la mejora del empoderamiento de personas de mediana edad con multicomorbilidad: ECA**", versión **1_19012023,** con código **CHUNSC_2023_06**, del que es Investigador Principal la Dra. LILISBETH PERESTELO PEREZ, ha sido evaluado por el Comité de Ética de la Investigación con medicamentos del Complejo Hospitalario Universitario de Canarias (Provincia de Santa Cruz de Tenerife) en su sesión del **26/01/2023**, y considera que:

Se cumplen los requisitos necesarios de idoneidad del Protocolo con los objetivos del estudio.

El procedimiento para obtener el consentimiento informado, incluyendo la hoja de información para los sujetos y el consentimiento informado, **versión 2, 13-03-2023** y la hoja de información al profesional y el consentimiento informado, **versión 2, 13-02-2023,** es adecuado.

La capacidad del Investigador y los medios disponibles son adecuados para llevar a cabo el estudio y no interfiere con el respeto a los postulados éticos.

Por todo ello, el Comité de Ética de la Investigación con medicamentos del Complejo Hospitalario Universitario de Canarias (Provincia de Santa Cruz de Tenerife) emite dictamen **FAVORABLE** para la realización de este estudio en el Servicio de Evaluación del Servicio Canario de la Salud (SESCS).

Secretario Técnico en funciones del CEIm
Complejo Hospitalario Universitario de Canarias

Servicio Canario de la Salud

Gobierno de Canarias

INFORMACIÓN ADICIONAL:

Es responsabilidad del investigador principal garantizar que todos los investigadores asociados con este proyecto conozcan las condiciones de aprobación y los documentos aprobados.

El Investigador Principal debe informar a la Secretaría del CEIm mediante una enmienda, informe anual de seguimiento o notificación, de:

• Cualquier cambio significativo en el proyecto y la razón de ese cambio, incluida una indicación de las implicaciones éticas (si las hubiera);
• Eventos adversos graves en los participantes y la acción tomada para abordar esos efectos;
• Cualquier otro evento imprevisto o inesperado, como desviaciones de protocolo;
• El cambio de Investigador Principal;
• Informe anual de seguimiento;
• La fecha de finalización del estudio;
• Informe final del estudio y/o publicación de resultados.