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):

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Informed consent for patients

(name and surname) declares:

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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: