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# EFFICHRONIC: Efficiency analysis of a self-management programme in 5 European countries, in vulnerable people with chronic diseases and/or their caregivers

**Submission date**
18/06/2018

**Recruitment status**
No longer recruiting

**Registration date**
20/06/2018

**Overall study status**
Completed

**Last Edited**
30/07/2025

**Condition category**
Other

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

## Plain English summary of protocol

Background and study aims
According to the World Health Organization (WHO), around 35% of women and 29% of men have a chronic disease and socio-economic factors, such as poverty and loneliness, have a big influence on how many people have chronic diseases. The cost of chronic conditions is up to 6.8% of the Gross Domestic Product in some European countries. In this study (EFFICHRONIC), the intervention is the Chronic Disease Self-Management Programme (CDSMP). This is a learning program for adults with a chronic condition and caregivers to encourage them to better manage and preserve their health. It was developed at Stanford University and has been positively tested for over 20 years already. The CDSMP intervention is expected to achieve greater advantages in people with a low socioeconomic position (SEP) or those who are isolated, because their disease progression is worse and they tend to adopt less healthy habits compared to citizens with a higher SEP. In the EFFICHRONIC project, pilot sites in five European countries (France, Italy, the Netherlands, Spain, and United Kingdom) apply the CDSMP intervention specifically in citizens with a low SEP and caregivers who live isolated lives.
The aim of EFFICHRONIC is to evaluate the benefits of the CDSMP intervention in vulnerable populations. The following questions will be answered:
1. What are the benefits of the CDSMP intervention on better managing one's life with regard to healthy lifestyle, handling emotions, correct medication intake, and quality of life?
2. What are the effects of the CDSMP intervention on the frequency of medical errors, the way people communicate with health professionals and the way they find and handle information on health?
3. What are the savings for society of the CDSMP intervention in terms of lowering healthcare use and improving work rate of the participants?
4. What is the grade of satisfaction with the CDSMP intervention of the participants?

Who can participate?
Adults with a chronic condition or caregivers with a low socio-economic level or who don't have a wide social network

What does the study involve?
The intervention consists of a series of 6 workshops, 2.5 hours each, which are held once a week for 6 weeks. The number of participants per workshop will be between 12 and 20. The participants will be evaluated by means of a self-administered questionnaire before the intervention and 6 months later. An important element of the intervention is education between equals. The workshops are conducted by 2 people, preferably one health professional and one person with a chronic condition. They are previously trained according to the CDSMP principles.

What are the possible benefits and risks of participating?
Participation in the study does not involve any risks or specific benefits, apart from the benefits of the CDSMP intervention itself. Data processing, communication and transfer will be done in accordance with the national regulation and, as of May 25, 2018, in accordance with the General Data Protection Regulation, the Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data. Only the research team and the health authorities, who have the duty to maintain confidentiality, will have access to all collected study data. Only information that cannot be identified may be transmitted to third parties. In the event of information transmission to other countries, it will be carried out anonymously with a data protection level according to the Regulation (EU) 2016/679.

Where is the study run from?
The study is coordinated from FICYT and CSPA in Asturias, Spain. The study will be conducted at the following European sites:
1. Centre Hospitalier Universitaire Montpellier (CHUM) in France
2. Ente Ospedaliero Ospedali Galliera in Genoa, Italy
3. Erasmus Universitair Medisch Centrum (EMC) in Rotterdam, the Netherlands
4. Foundation for the Promotion in Asturias of Applied Scientific Research and Technology (FICYT), Regional government of Health in Asturias (CSPA) and Asturias Public Health Service (SESPA) in Spain
5. QISMET, Portsmouth, United Kingdom

When is the study starting and how long is it expected to run for?
June 2017 to July 2020

Who is funding the study?
European Union Health Programme (2014-2020)

Who is the main contact?
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# Contact information

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## Additional identifiers

### Protocol serial number
738127 / EFFICHRONIC

## Study information

### Scientific Title
Enhancing health systems sustainability by providing cost-EFFIciency data of evidenced based interventions for CHRONIC management in stratified population based on clinical and socio-economic determinants of health

### Acronym
EFFICHRONIC

### Study objectives
Intervention programs in chronic disease patients within vulnerable populations, based on empowerment and self-care, selected taking into account the social determinants of health, are efficient and improve the sustainability of health services.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
1. In the UK, the study did not need approval from an ethics committee as it was considered to be measuring evaluation and not being investigational, as the effectiveness of the Chronic Disease Self-Management Programme has already been proven in previous studies.
2. Medical Ethics Committee Erasmus MC, 23/11/2017, MEC-2017-1116
3. Research Ethics Committee of the Principality of Asturias (Comité de Ética de la Investigación del Principado de Asturias), 31/01/2017, 20/17
4. Regional Ethics Committee of Liguria (Il Comitato Etico della Regione Liguria), 27/03/2018, 152-2018
5. In France, the Ethics Committee of the South-west and Overseas I (Comité de Protection des Personnes Sud-Ouest et Outre-Mer I) approved of the protocol (study number 9788) on November 5th 2018

## Study design
Quasi-experimental prospective multi-centre open-label before-after study

## Primary study design
Interventional

## Study type(s)
Quality of life

## Health condition(s) or problem(s) studied
Caregivers and people with chronic conditions in a vulnerable situation considering socio-economic and educational factors

## Interventions
The underlying conceptual elements of the Chronic Disease Self-Management Programme (CDSMP) programme are self-efficacy, empowerment, peer-to-peer education, recognition of the social determinants of health, salutogenesis (factors that support human health and well-being), community participation and risk stratification. The primary aim of the intervention is to achieve greater self-management of the chronic condition by changing the role of the passive citizen to empowerment in self-confidence and self-reliance. The intervention consists of a series of 6 workshops, 2.5 hours each, which are held once a week for 6 weeks. The number of participants per workshop is between 12 and 15. Generally, each workshop has between 7 and 8 activities with specific objectives, integrating different techniques (individual work, small and large groups, brainstorming), has an agenda and defined time for each activity, includes a break as a space where participants can start networking. Citizens with a chronic condition are encouraged to self-management by professionals as well as peers (other citizens with a chronic condition). One professional and one peer will volunteer to together lead a series of workshops. The leaders will be recruited and trained in the CDSMP principles. Participants will fill in a questionnaire before the intervention and 6 months later to evaluate the outcomes of the intervention.

## Intervention Type
Behavioural

## Primary outcome(s)

Change in quality of life as measured by the Physical and Mental Component Summary Scale scores of the 12-Item Short Form Health Survey (SF-12) between Day 0 and 6 months

### Key secondary outcome(s))

1. Health status and wellbeing assessed using change in score for the following questionnaires between Day 0 and 6 months:
1.1. Health status: change in score between Day 0 and 6 months in the EQ-5D-5L
1.2. Sleep and fatigue were measured separately with a visual numeric scale
1.3. Depression: Personal Health Questionnaire Depression Scale (PHQ)
2. Healthy behaviour assessed using change in score for the following questionnaires between Day 0 and 6 months:
2.1. Physical exercise: Exercise Behaviours questions (EB) and the International Physical Activity Questionnaires (IPAQ) (question 7)
2.2. Healthy eating measured by asking 3 questions on the usual intake of fruits, vegetables, and breakfast
2.3. Addictions: alcohol (Alcohol use disorders test-AUDIT) and smoking assessed by asking participants if they smoke (yes/no) at the time of the questionnaire
3. Communication:
3.1. Change in score between Day 0 and 6 months in communication with physician questionnaires (CP)
3.2. Percentage of positive answers on interpersonal communication skills at 6 months after the programme only
4. Self-management assessed using change in score between Day 0 and 6 months in the Self-Efficacy for Managing Chronic Disease (CDSE) scale.
5. National Health System confidence using percentage of positive answers on the confidence in the National Health System at 6 months after the programme
6. Health-economic assessment using change in score between Day 0 and 6 months in the SMRC Health Care utilization questionnaire and in the Productivity Cost Questionnaire
7. Treatment Adherence assessed using change in score between Day 0 and 6 months in the Short Medication Adherence Questionnaire (SMAQ)
8. Medical error experience assessed using change in score between Day 0 and 6 months on the question concerning medical error (AARP)
9. Critical thinkin assessed using change in score between Day 0 and 6 months in 2 items of the Consortium for the European Health Literacy Survey (HLS-EU)
10. Socio-familial assessment assessed using change in score between Day 0 and 6 months in the Gijón scale
11. Stratification of the participants by mortality risk using the self-administrated multidimensional prognostic indices (MPI-Chronic) at Day 0 and 6 months

### Completion date

31/07/2020

## Eligibility

### Key inclusion criteria

Isolated caregivers:
1. Takes care of someone with an illness
2. Vulnerability condition of isolation, such as (but not only):
2.1. Without means of transport or limited access to it
2.2. No Internet access
2.3. No or limited social support

Vulnerable people with a chronic disease:
3. Has a chronic disease (self-reported or clinically evaluated by medical staff) according to the International Classification of Primary Care (ICPC-2), i.e. a chronic pathology with code between 70 and 99 registered in one of the 17 chapters and more than 6 months of evolution
4. Has a vulnerability condition, such as (but not only):
4.1. Elderly (aged >65 years) living alone or in a nursing home
4.2. Prisoners
4.3. Ethnic minorities on a low income, i.e. finds it difficult to make ends meet
4.4. Legal immigrants on a low income, i.e. finds it difficult to make ends meet
4.5. Other vulnerable persons on a low income even if not included in the previous target groups

### Participant type(s)
Patient, Carer

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Sex
All

### Total final enrolment
2759

### Key exclusion criteria
1. Aged <18 years
2. Experiencing a period of crisis (domestic violence, refugees without a stable environment, eviction, etc)
3. Basic housing needs not met (homeless or roofless)
4. Diagnosed with severe mental health problems (according to DSM V, e.g. psychosis) with distorted perception of reality and/or inability to function in a group
5. Cognitive decline (e.g. Alzheimer's disease), identified as a score from 43 to 50 on the “Test Your Memory” test
6. Active addictive disorders (drugs, alcohol)
7. Inadequate knowledge of the language of the country of residence

### Date of first enrolment
01/08/2018

### Date of final enrolment
01/04/2020

## Locations

### Countries of recruitment

United Kingdom

England

France

Italy

Netherlands

Spain

**Study participating centre**
**Foundation For The Promotion In Asturias Of Applied Scientific Research And Technology – (FICYT)**
Oviedo
Spain
33007

**Study participating centre**
**Centre Hospitalier Universitaire Montpellier (CHUM)**
France
34295

**Study participating centre**
**Quality Institute For Self-Management Education And Training (QISMET)**
United Kingdom
PO6 4ST

**Study participating centre**
**Regional Government of Health in Asturias (CSPA)**
Oviedo
Spain
33006

**Study participating centre**
**Asturian Public Health Service (SESPA)**
Spain
33006

**Study participating centre**
**Erasmus University Medical Centre (EMC)**
Rotterdam
Netherlands
3015 GD

**Study participating centre**
**Ente Galliera Hospital (EOG)**
Genoa
Italy
16128

# Sponsor information

**Organisation**
Consejería de Sanidad del Principado de Asturias (CSPA)

**ROR**
https://ror.org/05mj4yh71

# Funder(s)

**Funder type**
Not defined

**Funder Name**
European Commission - European Union’s Health Programme

**Funder Name**
Consejería de Sanidad del Principado de Asturias (CSPA) - Regional Ministry of Health of the Principality of Asturias.

**Funder Name**
Servicio de Salud del Principado de Asturias (SESPA) - Public Health System of Asturias.

# Results and Publications

## Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date. All data shared during or after the project execution will be anonymized.

## IPD sharing plan summary

Data sharing statement to be made available at a later date

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 28/08/2021 | 21/09/2021 | Yes | No |
| Results article | Spain | 09/04/2024 | 30/07/2025 | Yes | No |
| Results article | outcomes | 21/08/2023 | 30/07/2025 | Yes | No |
| Protocol article | protocol | 18/12/2019 | 10/06/2020 | Yes | No |
| Other publications | design evaluation | 28/05/2019 | 01/10/2019 | Yes | No |
| Other publications | pilot study | 01/08/2019 | 01/10/2019 | Yes | No |
| Other publications | | 28/03/2024 | 02/04/2024 | Yes | No |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |
| Study website | Study website | 11/11/2025 | 11/11/2025 | No | Yes |