

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	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 20/06/2018	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 02/04/2024	Condition category Other	<input type="checkbox"/> 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?

Marta Pisano González

martam.pisanogonzalez@asturias.org

Study website

<http://effichronic.eu/>

Contact information

Type(s)

Scientific

Contact name

Dr Marta Pisano González

ORCID ID

<http://orcid.org/0000-0002-6485-9370>

Contact details

Ed Buenavista
Ala Oeste 2ª planta, sect izdo
C/ Ciriaco Miguel Vigil, 9
Oviedo - Asturias
Spain
33006
+34 985 66 81 53
MartaM.PisanoGonzalez@asturias.org

Type(s)

Scientific

Contact name

Mrs An LD Boone

ORCID ID

<http://orcid.org/0000-0001-5198-8889>

Contact details

Ed Buenavista
Ala Oeste 2ª planta, sect izdo
C/ Ciriaco Miguel Vigil, 9
Oviedo - Asturias
Spain
33006
+34 985 66 81 53
an.boone@asturias.org

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Non randomised study

Study setting(s)

Community

Study type(s)

Quality of life

Participant information sheet

Available upon request

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 measure

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

Secondary outcome measures

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

Overall study start date

01/06/2017

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

2000

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**

England

France

Italy

Netherlands

Spain

United Kingdom

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)

Sponsor details

Ciriaco Miguel Vigil, 9

Oviedo

Spain

33005

Sponsor type

Government

Website

<http://www.asturias.es>

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

Publication and dissemination plan

Current publication and dissemination plan as of 01/10/2019:

- Planned publication in minimum 5 high-impact peer-reviewed journals.

- Two Open Access articles related to the project have been published:

1. Pilotto A, Veronese N, Quispe K, et al. Development and validation of a self-administered Multidimensional Prognostic Index (SELFY-MPI) to predict negative health outcomes in community-dwelling persons. *Rejuvenation research* 2019; 22(4): 299-305. doi: 10.1089/rej.2018.2103.

2. Tan SS, Pisano MM; Boone AL et al., Evaluation Design of EFFICHRONIC: The Chronic Disease Self-Management Programme (CDSMP) Intervention for Citizens with a Low Socioeconomic Position. *Int. J. Environ. Res. Public Health* 2019, Volume 16, Issue 11, 1883. doi:10.3390/ijerph16111883.

3. Furthermore, we are planning to publish also the study protocol (which is under revision at this time) and at least three articles: on the recruitment strategies, the implementation of the selfy-MPI and the results of the project evaluation.

Added 10/06/2020: 3. Boone ALD, Pisano-Gonzalez MM, Valsecchi V, et al. EFFICHRONIC study protocol: a non-controlled, multicentre European prospective study to measure the efficiency of a chronic disease self-management programme in socioeconomically vulnerable populations. BMJ Open. 2019;9(12):e032073. Published 2019 Dec 18. doi:10.1136/bmjopen-2019-032073

Previous publication and dissemination plan:

- Planned publication in minimum 5 high-impact peer-reviewed journals.

- One article related to the project was published:

Pilotto et al. "Development and validation of a self-administered Multidimensional Prognostic Index (SELFY-MPI) to predict negative health outcomes in community-dwelling persons".

DOI: 10.1089/rej.2018.2103. Available online. Rejuvenation Research, 2018. Published in Open Access.

- One article was submitted to BMC Public Health on November 24th 2018: Tan et al. "Evaluation design of EFFICHRONIC: Enhancing health systems sustainability by providing (cost-) effectiveness data of an evidence-based intervention for chronic management in citizens with a low socioeconomic status". It is currently under editorial review.

- Furthermore, we are planning to publish at least the protocol, an article on recruitment strategies and the results of the project evaluation. We will provide you with more details once the publication process started.

Intention to publish date

30/12/2021

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?
Other publications	design evaluation	28/05/2019	01/10/2019	Yes	No
Other publications	pilot study	01/08/2019	01/10/2019	Yes	No
Protocol article	protocol	18/12/2019	10/06/2020	Yes	No
Results article	results	28/08/2021	21/09/2021	Yes	No
Other publications		28/03/2024	02/04/2024	Yes	No