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Implementing the concepts of mindfulness and community engagement to self-manage chronic diseases in four European cities

Submission date 15/06/2018	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 30/08/2018	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 28/10/2022	**Condition category** Circulatory System	[_] Individual participant data

Plain English summary of protocol

Background and study aims
Chronic illnesses are the main cause of death and disability in Europe, and they increasingly affect young and middle-aged people as well as the elderly, sometimes due to poor lifestyle choices. SEFAC takes a community approach to promoting health and reducing the burden of chronic ill-health. It was set up to help empower people to take control of their own health. It's like a grass-roots approach to health – getting volunteers and stakeholders involved in their own communities to help promote good habits and good health.

Who can participate?
Participants are people aged around 50 years and older who have a major chronic disease or who want to prevent chronic disease, and social/health professionals, pharmacists and volunteers who want to help create communities that promote health and the prevention and (self)-management of chronic diseases. Stakeholders are involved in the development and implementation of the SEFAC model right from the beginning and serve on the Advisory board as well.

What does the study involve?
The SEFAC intervention is based on the concepts of mindfulness, community engagement and ICT (information and communication technology) support. The intervention consists of a series of 3-7 workshops focusing on mindfulness . In parallel to the workshops, participants may opt to enroll in the social engagement programme of the SEFAC model. Finally, ICT support by means of the SEFAC app on a mobile phone was specially developed for SEFAC.

What are the possible benefits and risks of participating?
The programme helps people to build self-confidence, identify their goals and reach their dreams. This helps builds their social networks and makes them feel more connected to their communities, which makes them more resilient to chronic disease. There are no known risks of participating.

Where is the study run from?
Four regional pilot projects were set up, in Rijeka in Croatia, Treviso in Italy, Rotterdam in the Netherlands, and Cornwall in the UK, where a total of 360 citizens are participating in disease prevention and management activities. Volunteers are being trained to use a purpose-built 'Social engagement toolkit', and will in turn help care-givers, social workers, pharmacists and other stakeholders to put these activities into practice.

When is the study starting and how long is it expected to run for?
June 2017 to April 2021

Who is funding the study?
The study is funded under the European Commission's 3rd Health Programme.

Who is the main contact?
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Study website
sefacproject.eu

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
738202

Study information

Scientific Title
Social engagement framework for addressing the chronic disease challenge (SEFAC)

Acronym
SEFAC

Study objectives
We hypothesize that participants reported improvement regarding one or more outcomes including healthy behaviors and healthy lifestyle, empowerment, social engagement and self-management, and quality of life after 6 month of follow-up compared to the baseline. We furthermore hypothesize that acceptable intervention costs reduced overall costs in health and social care in the 4 pilot areas given SEFAC. We aim for a reach of >70% of citizens invited for chronic diseases risk screening; implementation of social engagement to reach the widest number of citizens making them more aware about their lifestyles and changing their habits and wellbeing in terms of physical, psychological and social integration to the local community; a decrease of not scheduled care services rather the scheduled one after 6 months of follow-up compared to the baseline measurements; and finally, an appreciation by stakeholders >7 on a 1-10 scale also about the ICT toolkit provided.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The study protocol has been approved by the Ethical Review Boards of all pilot sites.
1. The Ethical Committee - Faculty of Medicine University of Rijeka, 10/01/2018, 21T0-24-01-18_05
2. Comitato Etico per la Sperimentazione Clinica delle Province di Treviso e Belluno (CESC), 24/05/2018, 0104375
3. Medische Ethische Toetsings Commissie (METC) – Erasmus MC Rotterdam, 15/02/2018, MEC-2018-1047
4. UK Health Research Authority, 30/05/2018, REF 81/81

Study design
Non-randomised interventional trial

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Community

Study type(s)
Other

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Citizens at risk of or has coronary heart disease and/or type 2 diabetes mellitus

Interventions
1. The SEFAC model was designed and developed by SEFAC partners and based on the concepts of mindfulness, community engagement as well as ICT support. The model consists of a series of 3-7 workshops focusing on mindfulness . The workshops will be held once a week for 3-7 weeks and take 2 hours each . The first 3 'obligatory' workshops regard training mind and body for health and wellbeing, healthy habits and a healthy mindset. The following 1-4 workshops are 'voluntary'; they will focus on healthy eating, healthy physical activity, healthy relationships and healthy life with chronic conditions. Over these 3-7 workshops, participants learn to recognize the importance of knowing themselves and how to train the mind and body for health and wellbeing. Using mindfulness and compassion-based interventions integrated with change behavior practices, participants will have the opportunity to change for good and to develop self-efficacy and positive attitudes towards health. The workshops will be attended by a group of about 30 participants and will be delivered by professionals and volunteers. To this end, professionals and volunteers will be recruited and trained in the SEFAC mindfulness principles.
2. In parallel to the workshops, participants may opt to enroll in the social engagement programme of the SEFAC model. The social engagement concept of the SEFAC model was inspired on the Newquay Pathfinder Programme. The Programme has been described in detail elsewhere (http://knowledgebucket.org/our-story/). In short, guided conversations between a citizen and a volunteer aim to improve the quality of life for senior citizens in Newquay. These conversions help to identify ways to build self-confidence and self-reliance, providing practical

support to help achieve aspirations. The social engagement toolkit of Age UK Cornwall was adapted to the geographical, cultural and social context of the four pilot sites. The face-to-face conversations will be delivered by volunteers. To this end, volunteers from the community will be recruited and trained in the SEFAC social engagement principles.
3. Finally, ICT support by means of the SEFAC app on a mobile phone was especially developed for SEFAC. Participants will be asked to download the SEFAC app on their mobile phone and use it as ICT support for 6 months, starting from the first workshop session created for the SEFAC project. The SEFAC app incorporates elements of mindfulness and aims to improve behavioral change in lifestyles of, making participants healthier and at the same time more aware of the community as a resource, a target and an agent to adopt positive behaviors and a healthy life pattern. The figure below provides the foreseen interface of the SEFAC app and its functionalities. For example, one of the functionalities concerns the URICA assessment. The URICA assessment takes the stage of change of participants and individual emotional regulation ability into account. This behavioral change approach will help to define the individual coaching strands associated with the ICT support that will work according to the single profiling of the user's needs. Volunteers will support recruited participants in using the SEFAC app.

Intervention Type
Behavioural

Primary outcome measure
1. Self-management assessed using the short 6-item version of the Chronic Disease Self-Efficacy instrument (CDSE-6), which measures the confidence in one's ability to deal with health problems. It covers domains that are common across many chronic conditions, such as symptom control, role function, emotional functioning and communicating with physicians
2. Healthy lifestyle measured with six items on physical exercise (developed for the Stanford CDSMP intervention), three items on healthy eating (intake of fruits, vegetables, and breakfast), one item from the International Physical Activity Questionnaire (IPAQ) on sedentary behavior, one item on smoking and one item from the AUDIT-C on alcohol use
3. Depression measured with the 8-item Patient Health Questionnaire depression scale (PHQ-8)
4. Sleep and fatigue measured by visual analog scales (developed specifically for the Stanford intervention). Participants are asked to indicate how they experience the severity of their sleeping problems and fatigue during the last week on a scale from 0 (no sleeping problem /fatigue) to 10 (severe sleeping problem/fatigue)
5. Adherence to medication is measured with six items from the Short Medication Adherence Questionnaire (SMAQ), a short tool based on questions posed directly to the participant regarding his/her medication-taking habits
6. HR-QoL is measured with the 12-item short-form (SF-12) and the EQ-5D-5L instrument.. The SF-12 is a patient-reported survey which includes both a physical dimension (physical functioning, role-physical, pain and general health) and a mental dimension (vitality, social functioning, role-emotional, and mental health). The EQ-5D-5L is often used in health economics as a variable in the quality-adjusted life year calculation to determine the cost-effectiveness of an intervention. It has five dimensions: mobility, self-care, activity, pain and anxiety. Each dimension has five levels, ranging from no problems (level 1) to serious problems (level 5). Hence, EQ-5D-5L has 3,125 possible health states. Utility values for these health states are available for the pilot sites of each participating country. As part of the EQ-5D, participants are also asked to indicate their experienced current health state on a visual analog scale, 0 being the worst imaginable health and 100 being the best imaginable health.

Data will be collected from participants before the start of the first workshop session (baseline, T0) and 6 months (T1) later.

Secondary outcome measures
1. Prevalence of medical errors experienced is measured using 3 items from the American Association of Retired Persons (AARP) 'survey beyond 50.09' questionnaire
2. Communication with healthcare providers is measured with a scale of 3 items which measures the change in key behaviors concerning communicating with healthcare providers, a scale developed by the Self-Management Resource Center (SMRC)
3. Health literacy is measured with 2 questions from the Health Literacy Questionnaire (HLQ), which was designed using a validity-driven approach and which is used in many countries and in many settings
4. Healthcare utilization is measured with 4 questions from the SMRC Health Care Utilization questionnaire regarding doctor appointments, the use of hospital emergency rooms and hospital admissions
5. Productivity losses are measured with two domains from the Productivity Costs Questionnaire (PCQ): Lost productivity at paid work due to absenteeism (6 items) and lost productivity at unpaid work (3 items)
6. Various socio-demographic characteristics are measured, such as age, gender, country of birth, educational level and employment situation. Any additional remarks can be left in an open box at the end of the questionnaire

Data will be collected from participants before the start of the first workshop session (baseline, T0) and 6 months (T1) later. The T0 and T1-questionnaire will be almost identical, with the exception of six additional items which will measure the general satisfaction of the target population with the intervention. In the T1-questionnaire, three items will measure the experienced improvement in specific elements (problem solving, decision making, and confidence building), one additional item relates to the participants' confidence in their national health system, another refers to improvement of interpersonal communication skills and a sixth supplementary item rates the satisfaction with the whole intervention on a scale from 1 to 10.

Overall study start date
01/06/2017

Completion date
30/04/2021

Eligibility

Key inclusion criteria
1. Aged ≥18 years
2. Chronic condition (self-reported or clinically diagnosed by medical staff) defined as:
2.1. A chronic pathology with code between 70 and 99 registered in one of the 17 chapters of the International Classification of Primary Care (ICPC-2) 2.2. More than 6 months of evolution
3. Has caregiver
4. Low perceived self-efficacy (SEP)
5. Expected to be able to participate in the study for at least 6 months

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
360

Total final enrolment
447

Key exclusion criteria
1. Cannot adequately understand the information provided in the language of the country of residence
2. Experiencing a period of crisis (e.g. domestic violence, impending eviction)
3. Basic housing needs not met (e.g. being homeless)
4. Diagnosed with severe unstable mental health problems (accoring to DSM V; e.g. psychosis)
5. Active addictive disorders (e.g. alcohol addiction)
6. Cognitive decline (e.g. Alzheimer's disease)

Date of first enrolment
01/06/2018

Date of final enrolment
30/09/2019

Locations

Countries of recruitment
Croatia

England

Italy

Netherlands

United Kingdom

Study participating centre
SVEUCILISTE U RIJECI, MEDICINSKI FAKULTET
BRACE BRANCHETTA 20
RIJEKA
Croatia
51000

Study participating centre
Istituto per Servizi di Ricovero e Assistenza agli Anziani
Borgo Mazzini 48
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Study participating centre
Age Concern in Cornwall and the Isles of Scilly
Peat House, Newham Road
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Erasmus MC university medical center, Department of Public Health
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Sponsor type
Research organisation

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ROR
https://ror.org/018906e22

Funder(s)

Funder type
Not defined

Funder Name
Consumers, Health, Agriculture and Food Executive Agency

Alternative Name(s)
Chafea

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Publication and dissemination plan
The results will be disseminated by the project team through publications in scientific journals and conferences. The aim is to publish study outcomes in the course of 2021. To further disseminate the knowledge to all stakeholders the trialists will use the project website (sefacproject.eu). The European Local Inclusion and Social Action Network (ELISAN) is one of the partners of the UHCE project and aids the dissemination of project results to all stakeholders via social media.

Intention to publish date
31/07/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Hein Raat (h.raat@erasmusmc.nl)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	30/05/2019	03/06/2019	Yes	No
Results article		12/10/2022	28/10/2022	Yes	No