

Do Cardiac Health: Advanced New Generation Ecosystem

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The primary objective of Do CHANGE is to develop a health ecosystem for integrated disease management of citizens with high blood pressure and patients with ischemic heart disease or heart failure. The system will give them access to a set of...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Cardiac disorders, signs and symptoms NEC
Study type	Interventional

Summary

ID

NL-OMON43191

Source

ToetsingOnline

Brief title

Do CHANGE

Condition

- Cardiac disorders, signs and symptoms NEC

Synonym

cardiac disease; heart disease

Research involving

Human

Sponsors and support

Primary sponsor: Badalona Serveis Assisstencials

Source(s) of monetary or material Support: Europese Unie

Intervention

Keyword: Cardiac disease, ehealth, Health behavior, Lifestyle

Outcome measures

Primary outcome

In order for the intervention to be perceived as effective for patients it is important that behaviour changed leading to a healthy lifestyle is accomplished. In addition, an improvement in the patient reported outcomes (quality of life, anxiety-depression) would also indicate a clinical effect of the intervention.

Lifestyle: Changes in patients* lifestyle will be assessed by comparing (pre-post treatment) the sensor data from the tools that are used in the intervention. In addition, the Health Promoting Lifestyle Questionnaire (HPLP-II) will be administered to evaluate whether patients* subjective perception of lifestyle change has changed.

Behavioural flexibility: Whether the patients* behavioural flexibility (having a bigger behavioural repertoire which makes it easier to perform alternative behaviours) has increased and thus whether behaviour change (as conceptualized by Do Something Different program) has occurred will be assessed using purpose designed questions by the Do Something Different program.

Quality of life: Changes in quality of life will be assessed using the EuroQol-5D questionnaire. As this is a widely used instrument it will allow us

to integrate data from different partners.

Secondary outcome

Satisfaction with intervention: Whether patients were satisfied with the intervention in general, purpose designed questions will be administered.

Usability of the tools: To measure the perceived usability of the tools, the System Usability Scale will be administered (UTAUT).

Acceptance of tools: To assess patients* acceptance of the tools the Unified Theory of Acceptance and Use of Technology will be used (UTAUT) (59).

Willingness to pay: Because the monetary value of the tools is a significant factor for patients using the tools, we will assess patients* willingness to pay. For this purpose one part of the UTAUT will be used (Price Value). In addition, patients will be asked to list the price they would be willing to pay for the product.

Cost effectiveness: To assess the cost-effectiveness of the intervention the EQ-5D questionnaire will be assessed.

Health care consumption: Health care consumption will be assessed by purpose designed questions.

OTHER PARAMETERS

Depression: The Patient Health Questionnaire (PHQ-9) will be use to assess depression within the sample.

Anxiety: The Generalized Anxiety Disorder (GAD-7) questionnaire will be used to assess the levels of anxiety.

Type D personality: In order to assess whether the patients have a Type D (distressed) personality (tendency to experience negative affect; while at the same time being socially inhibited from sharing these feelings with others), the DS14 questionnaire will be administered.

Study description

Background summary

Cardiac diseases are the leading cause of death and a major health problem in Europe accounting for 47% of all deaths annually. Although pharmacological and medical treatment options for cardiac diseases have improved considerably over the last decades, there is increasing recognition that this strategy is neither sufficient nor sustainable to reduce disease burden and associated costs. By contrast, targeting modifiable risk factors, such as sedentary lifestyle, unhealthy diet, and psychosocial risk factors, may be a more sustainable strategy to reduce the disease and economic burden related to cardiac disease. The conventional medical approach tends to involve multi-disciplinary health-care professional teams compiling a care package based on the past history of the patient. This is likely to be determined at the case conference and it may be some months before the case is reviewed again. This activity is generally initiated and subsequently delivered by the general practitioner and who may then propose interaction with the dietician as required. For most personal e-health applications physiological parameters or symptoms are the primary * and often the only * means to determine the status and help to improve or manage the health of patients. The feedback on patient*s physiological condition is often not comprehensible for patients since the direct link with their everyday behaviour and experiences is missing. The Do CHANGE project approach differs from the conventional medical approach in that it focuses on assisting patients to increase their behavioural flexibility and subsequently their lifestyle. This is by providing them with specific information and alternative suggestions based upon their needs. The Do CHANGE project aims to combine concepts of behavioural change mechanisms with

technical tools that can capture physiological data.

Therefore the advantage of the Do CHANGE approach is that it provides methodologies for changing human behaviour by gathering physiological and symptomatic patient data to inform both the patient to enable self-management of their condition and the clinician to enable him to create a personalized care package for the patient. The Do CHANGE approach uses innovative technology that can be persistent, timely, specific, has access to enormous storage space and data, is multimodal, on the spot and efficient. It can easily be replicated and distributed (and thus standardized). The intention is that by changing behavioural habits and flexibility this will help patients to modify unhealthy habits.

In the Do CHANGE project, we address the needs of patients with coronary artery disease, heart failure, and hypertension whose condition often requires them to change their unhealthy lifestyle and decrease the cardiac risk factors.

Study objective

The primary objective of Do CHANGE is to develop a health ecosystem for integrated disease management of citizens with high blood pressure and patients with ischemic heart disease or heart failure. The system will give them access to a set of personalized health services in a near real-time fashion. This disruptive system will incorporate the behaviour change methods, such as *Do Something Different*, in conjunction with new innovative wearable/portable tools that can monitor behaviour and clinical parameters in normal living situations.

Primary objectives:

- To enhance behavioural habits and flexibility of patients with coronary disease, heart failure, or hypertension.
- To improve self-management and lifestyle
- To increase quality of life

Secondary objectives:

- Assess satisfaction, usability, and acceptance of the intervention(tools).
- To assess cost effectiveness of the intervention
- To evaluate changes in health care consumption

Exploratory:

- To assess subgroups who are more likely to benefit from the intervention based on their psychological, clinical, and demographic profile
- To examine whether the intervention is associated with physiological measures (e.g. ECG)
- To derive behavioural patterns of patients who participate by using anonymized GPS data

Study design

A randomized controlled trial study design will be used where patients will be randomized (1:1) to either the intervention group or the control group (usual care). Assessment will take place at 3 time points: baseline, 3- and 6 months post inclusion. Figure 1 provides a schematic representation of the trial design.

Intervention

Do Something Different programme

All patients randomized to the intervention group will receive the Do Something Different online programme which has been developed to change behavioural habits and flexibility of cardiac patients.

The Do Something Different Program has previously been developed and evaluated (ref). For the current study, the programme has been adapted to the population of interest (CAD, HF, and HT patients) together with behavioural experts and cardiologists. The program aims to change behavioural habits and increase flexibility and subsequently change habits associated with an unhealthy lifestyle and distress, which are both found to be associated with hypertension and cardiovascular risks. The program has been developed with input from cardiologists, psychologists, and patients. *Typical* other behavioural risks besides hypertension have been identified and are addressed within the program. To further adapt the program to patient* needs, all patient, prior to starting the program, will be assessed regarding their own functioning, distress, and personality such that the Do*s will match their personal habits and challenge them to change.

After assessing patients personality profile the intervention will be provided for 11 weeks. Patients will receive a total of 32 Do*s / messages during this period. The Do*s will be matched to their personal profile.

Patients will receive their Do*s through the care portal and/or via sms, depending on patients* preferences.

The Do Something Different programme is being used for behavior change purposes by various UK regions (for such things as diabetes, people who self-harm, as well as healthy living generally). In addition, it has been recognized by the UK Royal Society for Public Health by being given the RSPH award for Health & Wellbeing.

The award for Do Something Different is due to its innovative and creative approach in supporting behaviour change of individuals in Hertfordshire. Its digital platform is accessible and scalable with the potential for reaching large groups of people. Its interventions are underpinned by research and good practice in technology. RSPH 2015.

Moves app

For the future study within the Do CHANGE project, the Do Something Different programme wants to focus on providing *Contextual Do*s* where patients will receive behavioural prompts at the moment that the behaviour takes place. In order to reach this goal getting more insight in patients behavioral patterns is of utmost importance. Hence, that data will be gathered within this current

study as one of the exploratory objectives using GPS data. This will give us more insight and will be used as input for our future study. All patients participating in the intervention will be provided with the *Moves* app that will log their activities anonymously. This information will automatically be available for research purposes only. Patients will not receive any push messages from that app or any feedback.

Moves is an automatic diary of your life. Your daily storyline and maps show where, when, and how much you move. The application automatically records any walking, cycling, and running you do. The app is always active in the background, so there's no need to start and stop it. Just keep your phone in your pocket or your bag. The app consumes battery power, so nightly charging is recommended. With typical phone use, a smartphone running Moves should have enough battery power to last all day. The optional Battery Saving Mode in Moves for iPhone saves up to 40% of battery.

The Moves API can be used to build new apps, integrate with an existing service and visualise data. The API is designed for apps and services that have a server component. Individual users need to give permission to access data. However, providing any kind of personal information is optional, data collection can be done anonymously as well. Moves uses OAuth 2.0 for authentication and authorization and the actual authorization happens in the Moves app.

During this study the API can be used to collect location based data from participants. This data will be used to develop the location based responsive Do program. During the study participants will not receive feedback from the application. In the settings all notifications can be turned off. Besides, the app can be used without setting goals and accounts. The only thing a participant is asked is to install the app and fill in a unique code for data collection. Participants who do not use a smartphone or are not able to install the app do not have to use it.

N.B.! All collected location data will be anonymously collected without being able to trace the patients who are using the app.

Care-Portal

All patients who are randomized to the intervention group will also receive a Care-Portal (Docobo Ltd.) which will be installed at their home. The Care-Portal will be used to gather ECG data and blood pressure on a daily basis. The Care-Portal will send the physiological data directly to the cardiologist who will be able to access those via an online platform and contact the patient if necessary.

In addition, patients will receive their Do's through the care-portal.

The Care-Portal is a CE-marked device that has previously been successfully used and implemented to support patients with chronic conditions.

Blood pressure monitor

All patients in the intervention group will receive the digital blood pressure monitor *UA -767 Plus* which is a CE-marked device for clinical use (Appendix 1: product specification). Patients will be asked to measure their blood pressure on a daily basis and record the values through the care-portal.

Study burden and risks

Cardiac patients may benefit from this programme as it may enhance their skills to change their cardiotoxic lifestyle. The intervention is designed to support patients in their lifestyle change, hence we expect that patient randomized to the intervention arm will show an improvement in their lifestyle as compared to the comparator group. There is no risk associated with participation in the trial, as the intervention contains no invasive medical treatment. All the devices that will be used within the study are CE-marked for this purpose.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

age 18-75 years, newly diagnosed with CAD, HF or hypertension, having at least two of the following risk factors: smoking, positive family history, hypertension, increased cholesterol, diabetes, sedentary lifestyle, psychosocial risk factors. Patients should also have access to the Internet (and sufficient knowledge on using personal computer or smartphone), and have sufficient knowledge of the countries* native language.

Additional inclusion criteria for HF patients only is to have a left ejection fraction of $\geq 35\%$ and experience HF symptoms (e.g. shortness of breath, chest pain, exhaustion)

Exclusion criteria

significant cognitive impairments (e.g. dementia), patients who are on the waiting list for heart transplantation, life expectancy < 1 year, life threatening comorbidities (e.g. cancers), with a history of psychiatric illness other than anxiety/depression, patients who do not have access to internet, and patients with insufficient knowledge of the local pilot language (Dutch, Chinese and Catalanian).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	04-01-2017
Enrollment:	75
Type:	Actual

Medical products/devices used

Generic name: Care portal and bloodpressure monitor
Registration: Yes - CE intended use

Ethics review

Approved WMO
Date: 19-10-2016
Application type: First submission
Review commission: METC Brabant (Tilburg)

Approved WMO
Date: 07-11-2016
Application type: Amendment
Review commission: METC Brabant (Tilburg)

Approved WMO
Date: 21-11-2016
Application type: Amendment
Review commission: METC Brabant (Tilburg)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL57411.028.16