Do Cardiac Health Advanced New Generation Ecosystem 2

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

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

Summary

ID

NL-OMON44217

Source
ToetsingOnline

Brief title
Do CHANGE 2

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 programme) has occured will be assessed using purpose designed questions by the Do Something Different programme.

Quality of life: Changes in quality of life will be assessed using the EuroQol-5D questionnaire. As thisis 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)

Willingness to pay: Because th emonetary 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.

Satisfaction with the intervention; usability and acceptance, and willingness to pay will qualitatively be assessed and with the above mentioned questionnaires.

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 sued to assess depression within the sample.

Anxiety: The Generalized Anxiety Disoder (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 bloodpressure 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 improve self-management and lifestyle
-To increase quality of life
-To improve behavioral habits and flexibility of patients with coronary disease, heart failure, or hypertension.

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 physiological measures (e.g. ECG, Blood pressure, weight) improve (in the intervention group)
-To gain more insight in patients* sleep patterns and physical activity (in the intervention group)

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.

Intervention

1. 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 (www.dsd.me). 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.

In addition to the core programme a patient may receive up to two Responsive Do*s (also referred to as ToDo*s) per week. Whether a patient receives one of these ToDo*s, and which one is selected, is determined by analysis of data collected from the sensor devices the patient has opted in to use (e.g. the Fitbit). Patients who tend to have a sedentary lifestyle as indicated by their Fitbit will receive ToDo*s that will encourage them to break with these negative habits and increase their physical activity.

There is a theoretical maximum of receiving 16 ToDo*s during a programme, but the average would be less.

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

2. CarePortal
All patients who are randomized to the intervention group will also receive a CarePortal (Docobo Ltd.) which will be installed at their home. The CarePortal will be used to gather ECG data, address symptomatic data, blood pressure, and weight on a daily basis. The patient will be able to take the ECG measure at any time. By touching the screen of the CarePortal the instructions to take the measure will appear, guiding the patient step by step to take the ECG (which all will take 2 minutes). The CarePortal 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. Further to that the patients will receive questions addressing the daily symptoms of their condition.

3. Moves App
Do Something Different programme will providing *Contextual Do*s* /behavioural prompts at the moment that is most relevant to the patient. In order to reach this goal getting more insight in patients behavioral patterns is of utmost importance. 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 and to third parties as described in the *terms of use* document which will be provided as supplement file to the patients. 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.

4. Beddit
To log patients* sleep data and evaluate whether their sleep patterns have improved over time due to the intervention, patients assigned to the intervention group will all receive the Beddit device (www.beddit.com). Beddit is a certified medical device to measure sleep, heart rate and breathing during time spend in bed. The devices has been validated (Paalasmaa, J., 2014 PhD thesis. University of Helsinki) and is considerd one of the most accurate devices to monitor sleep. For the current strial the *Beddit 3* will be used. Beddit 3 is thin device that is hidden under your sheet. The patients are not required to carry any tools with them. The Beddit transfers information via Bluetooth to the Beddit app that the patient will have on their phone. This data is in addition transferred to the Do CHANGE App where the patient will be able to see their own data. Simultaniously the data is also stored at the consortium servers (at TU/e, Docobo, and ONMI)

5. Fitbit
Patients* physical functioning will be assessed using a Fitbit. With this device we will be able to examine whether patients* sedentary lifestyle has changed due to the intervention. With the Fitbit patients step count, physical activity, heart rate, calories burned, distanced walked, number of stairs climbed will be assessed. This information will not only be available for patients to get more insight in their functioning (and for research purposes), but will also be used as input to generate ToDo*s from the Do Something Different programme as mentioned before. For the current trial *Fitbit Alta HR* will be used.

6. CookIT:
Is a smart spatula that is able to monitor patients cooking behavior (whether patients are using the spatula) and estimate the sodium concentration of the food being prepared. The CookiT has been developed by ONMI and Eurecat as part of the Do CHANGE project. .

7. Vire app
In order for patient not to feel overwhelmed by the apps that they will have to check everyday (if they are interested in their own progress) the Do CHANGE app has been developed. The Do CHANGE app has been developed together with end users and input from health care professionals. This app is able to provide an overview of all the devices that the patients will be using during the study (e.g. Beddit, Fitbit, etc.). Through this app patients will also be able to

receive the Do*s from the Do Something Different programme. The app has been developed to help the patients get an integrated overview of their own data. No addition data will be collected through the Do CHANGE app, the dData coming in from the devices that will be integrated in this app (Moves, Beddit, Fitbit, Do Something Different) will be stored as previously mentioned at the consortium servers at TU/e, ONMI, and Docobo.
The Do CHANGE app will have an additional function which will enable the patients to collect (and share with their health care provider) pictures of their food. By simply taking a picture with this app the pictures will be uploaded to the health care professional portal and the health care professional will be able to see what the patient ate.

8. Dependent on the main heart condition, the patient will decide together with the healthcare professional what additional devices the patient will be using .

- FluIT: FluiT is a tool to assess fluid intake during the day. This device has previously been developed and is currently being using in another clinical trial in the Catharina Hospital in Eindhoven.

- Bloodpressure 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. Patients will be asked to measure their blood pressure on a daily basis and record the values through the care-portal.

-Scale: If needed patients will be provided with a weight scale to monitor their weight on a daily basis. For the current trial the *Seca Aura 807* model will be used. Patients will be able to communicate their weight on a daily basis through the care portal. This information will also be visible in the health care professional portal which is accessible for the patients* cardiologist.

All patients in the intervention group will be approached between month 3 and 6 to provide kwalitative data about the satisfaction with the intervention. With this information we will be able to further personalize the programme.

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 copared to the comparator group. There is no risk associated with participation in the trial, as the intervention does not entail invasive medical treatment. The

intervention consists of a behavioural intervention, and the technological applications used for this purpose are all CE marked or approved by the IGZ.

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, 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 have a smartphone (and sufficient knowledge on how to use a personal computer or smartphone), and have sufficient knowledge of the countries' native language. Additional inclusion criterium for HF patients only is to experience HF symptoms (e.g. shortness of breath, chest pain, exhaustion)

Exclusion criteria

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

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:	Pending
Start date (anticipated):	02-07-2017
Enrollment:	75
Type:	Anticipated

Medical products/devices used

Generic name:	CarePortal;Bloodpressure monitor;scale;CookIT;FluIT;Beddit;Fitbit
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	25-07-2017
Application type:	First submission

Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	02-11-2017
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	NL61660.028.17