

BENEFIT for all: The Ecosystem for Healthy Living

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20054

Source

Nationaal Trial Register

Brief title

BENEFIT

Health condition

Cardiovascular disease

Sponsors and support

Primary sponsor: Leiden University, LUMC, Vital10

Source(s) of monetary or material Support: We acknowledge the support from ZonMW and the Netherlands Cardiovascular Research Initiative: An Initiative with support of the Dutch Heart Foundation, CVON2016-12 BENEFIT.

Intervention

Outcome measures

Primary outcome

1. (Maintenance of) Healthy lifestyle behavior in five domains: physical activity, smoking, alcoholic beverage consumption, diet, stress and stress-management activities, and sleep.

Secondary outcome

1. Physical health: relevant CVD risk factors such as cholesterol, diabetes, abdominal circumference, blood pressure and weight.
2. Quality of life: physical functioning, role functioning, social functioning, mental health, health perceptions and pain.
3. Cost-effectiveness: economic evaluation in terms of cost-per quality-adjusted life-year (QALY) taking into account mobility, ability to self-care, ability to undertake usual activities, pain/discomfort, and anxiety/depression.

In addition we will explore the following:

1. Psychosocial health: depressive symptoms, anxiety symptoms and social support.
2. Motivation and self-efficacy: patients are requested to formulate at least one specific lifestyle goal in one of the six healthy lifestyle behavior domains. Outcome is the patient's level of (intrinsic and extrinsic) motivation and self-efficacy to reach this goal and the patients' stage-of-change he/she is in.
3. BENEFIT intervention evaluation: degree of therapy compliance, platform use, engagement and satisfaction with the digital platform

Study description

Background summary

Engaging in a healthy lifestyle may prevent cardiovascular disease (CVD). To promote initiating and maintaining a healthy lifestyle among CVD patients, the BENEFIT for all intervention was developed as an addition to standard, face-to-face, cardiac rehabilitation care. This intervention consists of a multifaceted lifestyle modification program that rewards patients for the time and energy spent on healthy lifestyle activities. Core element of the intervention is the unlimited access to an advanced digital platform with a personal health environment (PHE) that allows for day-to-day goal monitoring, admittance to evidence-based lifestyle interventions, personal coaching and a gamified loyalty program. By rewarding a broad range of health behaviors (such as exercising, abstaining from smoking) and adherence behaviors (attending prevention programs, showing up for health appointments) the program aims to integrate care and non-care settings and facilitate embedding the new lifestyle in everyday life. Importantly, this multilayered program ensures involvement of all stakeholders- from patients and healthcare professionals to private partners and smart technology developers- all working closely together. The goal of the current study is to examine the added value of the BENEFIT intervention (i.e., additionally providing CVD patients with a PHE next to standard cardiac rehabilitation care) on the maintenance of healthy lifestyle behaviors. The BENEFIT intervention is evaluated using an adjusted stepped-wedge randomized cluster design, as this design is best equipped to evaluate (continuously developing) healthcare innovations. We aim to include 600-700 patients in 6 cardiac rehabilitation centers over a period of two years. Following a stepped-wedge roll-out, all centers start with a 'natural baseline' period (i.e., control condition) in which care-as-usual is

provided to patients, before centers cross over- one-by-one- to the intervention condition by additionally providing patients with a PHE. Data is collected at baseline (before start of cardiac rehabilitation), after three months (end of cardiac rehabilitation) and at one year follow-up. Our primary outcome is lifestyle improvement: the program's main objective is that more patients who participate in the intervention program, compared to patients who receive care-as-usual, will maintain the health behavior most relevant to them for at least one year. Secondary outcomes are improvements in physical health (CVD risk factors), quality of life (RAND SF20), and cost-effectiveness (EQ-5D). The change in outcome measures over time and between conditions is examined using regression analyses that take into account the nesting of patients within centers. In addition, we examine platform use by means of log data analysis. User engagement and satisfaction with the BENEFIT program are assessed by means of usability tests and interviews.

Study objective

Main hypothesis

The BENEFIT intervention will significantly increase the number of CVD patients that can maintain the healthy lifestyle behavior most relevant to them for at least one year, compared to care-as-usual.

Secondary hypothesis

The BENEFIT intervention will significantly increase physical health (i.e., cardiovascular risk factors), quality of life, and cost effectiveness, compared to care-as-usual.

In addition, to better understand the main findings, we will explore the following topics:

- The association of physical and mental health, quality of life, motivation, self-efficacy, and support with lifestyle behavior maintenance in general.
- The impact of the BENEFIT program on mental health, motivation, self-efficacy and social support.
- Platform use, engagement and satisfaction with the BENEFIT program.
- Differences in intervention effects for specific subgroups (e.g., gender, SES) and specific lifestyle goals (e.g., exercise, dieting, alcohol consumption, smoking, stress management, sleep).
- Possible indirect effects. For example, the indirect effect of physical and mental health, quality of life and social support at baseline on 3-month follow-up of motivation and self-efficacy, affecting 1-year follow-up of healthy lifestyle outcome measures. In addition, we are also interested in the indirect effects of the intervention on physical health through healthy lifestyle behaviors.
- Predictors of study, cardiac rehabilitation, and PHE drop-out and adherence.

Study design

With the exception of the usability tests and interviews to measure engagement and satisfaction with the digital platform, the current study will only utilize data that is routinely assessed for all patients following cardiac rehabilitation, either by healthcare professionals or through the digital platform. Filling in the questionnaires is part of the standard cardiac rehabilitation care. Data are collected at the start of the study (before the standard cardiac

rehabilitation program starts), after three months (when the standard cardiac rehabilitation program ends) and at one year follow-up.

Intervention

The BENEFIT intervention is a multifaceted lifestyle modification program that is offered in addition to standard, face-to-face, cardiac rehabilitation care. The program utilizes environmental rewards and reinforcement strategies to promote initiating and maintaining a healthy lifestyle by rewarding patients for the time and energy spent on healthy lifestyle activities. Core element of the intervention is the unlimited access to an advanced digital platform with a personal health environment (PHE) that allows for day-to-day goal monitoring, admittance to evidence-based lifestyle interventions, personal coaching and a gamified loyalty program. Goal of the PHE is to increase uptake and adherence to a healthy lifestyle both during and after the face-to-face treatment in cardiac rehabilitation. The digital platform is interactive and personalized for every user based on information patients provided during cardiac rehabilitation (e.g., information concerning goals, health, motivation, self-efficacy, social support). On their PHE, patients are provided with an overview of digital lifestyle intervention programs of external parties, all of which are based on evidence-based principles. Patients can then monitor their physical health and goal progress by using sensors and devices linked to the patient's PHE (e.g., steps from a step counter, CO values from a CO meter). Finally, a healthy lifestyle is promoted through a loyalty program. BENEFIT loyalty points can be earned for a broad range of health behaviors, such as exercising, abstaining from smoking, attending prevention programs, and showing up for health appointments. BENEFIT loyalty points can be redeemed for discounts on healthy products (e.g., groceries) or discounts on family outings. By rewarding everyday lifestyle and adherence behaviors, the program integrates care and non-care settings and facilitates embedding the new lifestyle in everyday life.

Contacts

Public

Leiden University
Andrea Evers

+31 71 527 6891

Scientific

Leiden University
Andrea Evers

+31 71 527 6891

Eligibility criteria

Inclusion criteria

Patients referred to cardiac rehabilitation (i.e., people who have had a heart or brain incident, or who, according to Dutch guidelines, have an increased risk of cardiovascular disease of $\geq 10\%$)

Exclusion criteria

1. People with severe somatic and / or psychiatric co-morbidity which impedes participation according to the care provider's judgment.
2. People who do not have an email address and/or people who do not have the necessary digital skills to use their email address and fill out online questionnaires.
3. Non-Dutch speaking persons

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	13-01-2020
Enrollment:	650
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date: 09-03-2020

Application type: First submission

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
NTR-new	NL8443
Other	METC-LDD : N19.040

Study results

Summary results

Keesman M, Janssen V, Kemps H, et al. BENEFIT for all: An ecosystem to facilitate sustained healthy living and reduce the burden of cardiovascular disease. Eur J Prev Cardiol 2019;26(6):606-08. doi: 10.1177/2047487318816388