Evaluation of a PReparatory eHealth intervention for patients in CArdiac REhabilitation: a pilot study.

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To assess the feasibility of a tailored eHealth intervention (primary) for cardiac patients with a low socio-economic position and explore its effect on patient activation, certainty and guidance (secondary) compared to usual care.

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

Summary

ID

NL-OMON51403

Source
ToetsingOnline

Brief title
PReCARE

Condition

- Cardiac disorders, signs and symptoms NEC

Synonym
Cardiovascular disease, Heart disease

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W,Capri Hartrevalidatie

Intervention

Keyword: Cardiac Rehabilitation, eHealth, Preparation, Socio economic position

Outcome measures

Primary outcome

Feasibility of the intervention in terms of usage, acceptability and experience.

- Usage will be determined based on the number of days used, length of use (period from first to last day use), number of viewed messages and time spent per visit.

- Acceptability will be measured using a self-designed questionnaire (9 items) based on the USE questionnaire (Usability, Usefulness and satisfaction)

- Experience will be determined based on a thematic analysis of several qualitative semi-structured interviews.

Secondary outcome

- Patient activation measured using the PAM-13 questionnaire. We use the Dutch translation of this questionnaire consisting of 13 items with a 4-point Likert scale.

- Feelings of certainty and guidance using a self-designed questionnaire (9 items).

Study description

Background summary

Health disparities between socioeconomic classes are growing. Certain neighbourhoods with a lower socio-economic position (SEP) display generally a

higher prevalence of unhealthy lifestyles. A possible cause is lower levels of patient activation (being able to manage your health). Improving patient activation for some groups therefore seems important to facilitate their success within their cardiac rehabilitation. In a preliminary study we found that patients indeed have a passive attitude towards their condition, especially during the so-called *waiting period* (the period between discharge from the hospital and start of the rehabilitation). Activating patients in this period could be beneficial for the success of their upcoming rehabilitation as well as their long-term health. Therefore, we have developed a tailored eHealth intervention aimed at improving patient activation levels by supporting patients with a low SEP during their waiting period.

Study objective

To assess the feasibility of a tailored eHealth intervention (primary) for cardiac patients with a low socio-economic position and explore its effect on patient activation, certainty and guidance (secondary) compared to usual care.

Study design

Randomised pilot study

Intervention

Patients will be enrolled in the intervention group based on randomization. The intervention group will use an eHealth application during the waiting period before cardiac rehabilitation starts. The app asks patients to engage with preparatory messages daily. Messages are pre-made and consist of videos about the rehabilitation, written tips and spoken success stories. The control group will go through the usual waiting period before the start of cardiac rehabilitation.

Study burden and risks

Both intervention and control group will receive CR as usual, as recommended by guidelines. Before CR starts, participants in the intervention group are asked to use an eHealth application daily. The app shows daily messages provided by representatives of different disciplines within CR. Use of the app per day depends on the length of messages but can range between 5 and 10 minutes per day. The content of the app is developed in collaboration with healthcare workers at the rehabilitation center. Patients in the control group do not have this eHealth application in their waiting period.

Both groups will be asked to fill in a questionnaire at two moments during their rehabilitation:
T1: Face-to-face group meeting within one week after signing enrollment in CR

(rehabilitation agreement) about demographics, certainty, guidance and activation consisting of 25 questions and taking approximately 8 minutes.
T2: At the start of the rehabilitation (usually after 2 to 6 weeks from T1) about:
Control: Certainty, guidance, and activation consisting of 22 questions taking approximately 7 minutes.
Intervention: Acceptability, certainty, guidance, and activation, consisting of 31 questions and taking approximately 10 minutes

To minimize the burden for participants, at the start of the study, participants can indicate their preferred medium for filling in the questionnaires (email or postal mail) for T2. Additional semi-structured interviews (regarding experience, 30 minutes) will be held at T2 with a subset (estimated: N * 10) of the participants in the intervention group. Participants are free to choose where they want to do the interviews, either at the CR center, or at their home. Finally, to minimize the burden of the participants using the intervention, we will clarify that reading the messages is not obligatory and that they can be read at any time during the day.
We take additional precautions regarding the SEP of our participants: we will be clear about the nature of the research while avoiding stigmatization. We will do this by avoiding words that imply marginalization in our communications (e.g. IC form). We will ensure our communications, written as well as verbal, are clear and understandable.

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

Patients with a low socio-economic position who are eligible for participation in cardiac rehabilitation and who are referred by their cardiologist to Capri Hartrevalidatie.

Exclusion criteria

Patients with severe physical, psychological, or cognitive impairments.

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:	Recruitment stopped
Start date (anticipated):	08-02-2023
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	07-12-2022
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	21-03-2023
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL81969.078.22