TIMELY: A patient-centred lifestyle program to support the continuum of care in patients with coronary artery disease using eHealth and artificial intelligence

Published: 16-06-2023
Last updated: 30-11-2024

1. To investigate whether the TIMELY intervention is superior to usual care in terms of A) reducing the CoroPredict risk score (indicating risk of 10-year mortality: primary biomedical outcome) from baseline to six months; andB) increasing...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Coronary artery disorders
Study type	Interventional

Summary

ID

NL-OMON53970

Source
ToetsingOnline

Brief title
TIMELY

Condition

- Coronary artery disorders

Synonym
coronary artery disease, heart disease, ischemic heart disease

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit van Tilburg
Source(s) of monetary or material Support: Europese Commissie

Intervention

Keyword: Artificial intelligence, Coronary artery disease, eHealth, Health behavior

Outcome measures

Primary outcome

1. To investigate whether the TIMELY intervention is superior to usual care in

terms of

A) reducing the CoroPredict risk score (indicating risk of 10-year mortality:

primary biomedical outcome) from baseline to six months; and

B) increasing functional fitness levels (6-minute walk test) primary

behavioural outcome) from baseline to 6 months

Secondary outcome

The improvements under primary objectives are expected to be associated with

improvements in the secondary outcomes:

a. Physical activity levels and cardiovascular responses to exercise

b. Healthy dietary habits

c. Smoking cessation

d. Medication adherence

e. Reducing psychological stress levels

1. To investigate whether the TIMELY intervention is superior to care as usual

in terms of improvement in physical and mental well-being and quality of life

2. To investigate the feasibility and usability of the TIMELY intervention.

3. To investigate whether the TIMELY intervention is superior to care as usual

in terms of cost-effectiveness

Study description

Background summary

Cardiovascular diseases (CVD) are the leading cause of death globally according to the WHO. The highest burden of disease among CVDs is caused by coronary artery disease (CAD). Ageing predisposes patients to a high incidence and prevalence of CAD, in both men and women. Older patients have the greatest mortality and morbidity risk attributable to Chronic Coronary Syndromes (CCS), partially due to the high prevalence of comorbidities.
Secondary prevention through comprehensive cardiac rehabilitation (CR) has been recognized as the most cost-effective intervention to limit the physiological and psychological effects of CVDs and reduce the risk of future cardiovascular events. Contrary to pharmacological or invasive interventions for CAD, CR is far from being well implemented in all European countries and participation rates in available programs range between 30-50% of eligible patients.

The TIMELY platform has been developed to stimulate a healthy lifestyle after CR. Patient-related barriers for digital health mainly involve the usability of the CR platform, especially for older patients. Thus, TIMELY includes digital tools and interfaces that will not hinder senior citizens from using them, as patient co-design has guided the development.

Since lifestyle changes are key in the prevention and self-management of CAD, the main component of the TIMELY platform will be an app built on behavioral change techniques and models to empower and motivate patients to adopt a healthy lifestyle. Artificial intelligence (AI) will be employed to adapt the platform to the most current needs of the patient. In addition to prevention and self-management, the TIMELY platform will constantly monitor and predict the individual risk for disease progression or serious events and complications using validated risk scores (CoroPredict®). Next to monitoring physical health, mental health will be assessed using AI chatbots.

TIMELY will become the first AI-powered, patient-centered eHealth platform that continuously adapts and customizes CR to meet the needs of patients.

Study objective

1. To investigate whether the TIMELY intervention is superior to usual care in terms of
A) reducing the CoroPredict risk score (indicating risk of 10-year mortality: primary biomedical outcome) from baseline to six months; and
B) increasing functional fitness levels (6-minute walk test); primary behavioural outcome) from baseline to 6 months

Study design

A randomized controlled trial study design will be employed, where patients will be randomized (1:1) to either the control group receiving usual care or the intervention group, where patients will receive usual care in combination with the TIMELY intervention. Assessment will take place at 4 time points: baseline, 3, 6 and 12 months post inclusion.

Patients will be asked to fill out questionnaires at 4 timepoints: baseline, 3 months, 6 months and 12 months. Through the TIMELY-platform (app) patients in the intervention group will receive prompts to conduct and ECG and blood pressure measurement. Patient in the intervention group will be wearing a Garmin, which collects information about their physical activity patterns. Lastly, patients will receive physical assessments at three time points (baseline, 6 months and 12 months), namely an exercise test and bloodwork will be done.

Intervention

1. Timely app
The TIMELY app will help patients adjust their lifestyle in order for them to become healthier. The TIMELY app is supported by artificial intelligence and is based on behavioral change techniques. Through the chatbots the messages aimed at changing the behavior of patients will be personalized. Specific attention will be given to promoting physical activity. Because the chatbots can take the (physical) context of the patient into account, the odds of success are higher.
2. Wrist-worn activity tracker
Patients will receive an activity tracker, which will collect physical measures, such as level of activity, heart rate and sleep.
3. Tel-O-Graph
Patients will receive a blood pressure monitor, the Tel-O-Graph. The device additionally measures other hemodynamic parameters through pulse wave analysis (PWA).
4. Net_ECG
Patients will receive an easy-to-use device capable of registering atrial fibrillation.
5. eConnect HUB
Patients will receive the eConnect HUB which will transfer all data from the Tel-O-Graph and the Net_ECG to the researchers.

Study burden and risks

Patients will complete questionnaires at 4 timepoints: baseline, 3 months, 6 months and 12 months. In addition, patients will have conversations with the chatbots in the app and, based on this, receive encouragement to perform certain behaviours (e.g. exercise more or eat healthier). Through the TIMELY platform (app), patients will receive messages to take their ECG and blood pressure readings. Furthermore, patients will wear a Garmin, which will collect information about their exercise behaviour. Finally, at the three measurement moments, patients will receive various physical examinations, namely exercise tests. Blood will also be drawn at these times.

There are no risks associated with the TIMELY intervention. However, there are risks associated with the blood test and the exercise test. In rare cases, cardiac arrhythmias occur during the exercise test. However, this can be dealt with immediately if necessary. The risks associated with this amount of blood sampling are small. A patient may experience pain or bruising. The amount of blood we draw is not enough for patients to feel limp. In very rare cases, patients may experience a haematoma or damage to a nerve. Because patients have had blood drawn before without these problems, the chances of this happening are very low.

The patient is exposed to minimal risks and the time investment is minimal. Learning how to use the medical devices and then integrating them into regular use will not take much time. Filling out the questionnaires will also not take much extra time. The physical examinations will take place three times. This will still take the most time, but this outweighs the possible benefits (insight into own functioning, development of better lifestyle, better quality of life).

Contacts

Public
Universiteit van Tilburg

Warandelaan 1
Tilburg 5037AB
NL
Scientific
Universiteit van Tilburg

Warandelaan 1
Tilburg 5037AB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

(1) Age 18 years and over (there is no a priori upper age limit); (2) Documented stable CAD and referred to cardiac rehabilitation (at > 2 weeks but < 10 weeks after PCI or > 4 weeks but <12 weeks after CABG or MI: STEMI or non-STEMI), and/or having documented CAD by coronary angiography (stenosis in a major coronary artery > 50%); (3) Access and ability to operate a smartphone; (4) Able to speak the country*s native language.

Exclusion criteria

(1) Unable to fully understand the provided study information and consequences of participating in the study; (2) presence of a physical impairments interfering with the use of the app or devices (e.g., blindness, wheelchair bound); (3) known diagnosis of an active malignant tumors (cancer) or any other medical condition associated with an expected life expectancy of less than one year; (4) Unstable cardiovascular, cerebrovascular or other unstable medical conditions; (5) Refusal to informed consent; (6) Having a pacemaker.

Study design

Design

Study type:	Interventional
Intervention model:	Other

Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	08-02-2024
Enrollment:	120
Type:	Actual

Medical products/devices used

Generic name:	Timely
Registration:	No

Ethics review

Approved WMO Date:	16-06-2023
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	04-04-2024
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	NL82723.028.23