Adherence to a Lifestyle Monitoring System in Patients with Heart Disease

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The primary objective of this project is to assess the adherence to a patient-centred integrated lifestyle monitoring system that tracks daily physical activity levels, dietary habits, mental stress and sleep quality.

Ethical review	Approved WMO
Status	Completed
Health condition type	Cardiac disorders, signs and symptoms NEC
Study type	Observational non invasive

Summary

ID

NL-OMON50694

Source
ToetsingOnline

Brief title
Care-On

Condition

- Cardiac disorders, signs and symptoms NEC

Synonym
Coronary artery disease and atrial fibrillation

Research involving
Human

Sponsors and support

Primary sponsor: Maxima Medisch Centrum
Source(s) of monetary or material Support: De Hartstichting,Philips

Intervention

Keyword: Adherence, Heart disease, Lifestyle, Telemonitoring

Outcome measures

Primary outcome

The primary endpoint is the adherence (i.e., the % of participants still using a patient-centred lifestyle monitoring system at 1-year follow-up).

Secondary outcome

The secondary endpoints are:

- Usability will be measured using the System Usability Scale (SUS) score and success rate.
- To measure the correlation of demographic and disease characteristics, quality of life, self-efficacy, depressive symptoms, anxiety, motivation, stage of change, fatigue, physical fitness, levels of metal stress, use of a goal tracking functionality, use of the sharing functionality with external contacts, perception of system usability and prior experience with technology with adherence. Standardized questionnaires will be used for self-report measures and objective ambulatory measures from the lifestyle monitoring system for objective lifestyle measures.
- The association between adherence with clinical outcomes will be examined by evaluation patient clinical records (clinical events) and standardized self-report data (quality of life).

Study description

Background summary

In cardiac rehabilitation (CR), technological innovations can help to improve patient relevant outcomes and reduce health care costs. Lifestyle and psychological wellbeing are considered pivotal in this field as physical fitness, daily physical activity levels, dietary habits, mental stress, sleep quality and smoking habit, are strongly related to the occurrence, clinical course and overall treatment outcomes of common cardiovascular diseases (CVD*s) such as coronary artery disease (CAD) and atrial fibrillation (AF). In fact, quality of life is often not improved after major cardiac interventions and persistent unhealthy lifestyle factors have adverse effects on the clinical course of patients with coronary artery disease and atrial fibrillation. However, despite their undisputed relevance, these lifestyle factors are currently not objectively and subjectively monitored and therefore not optimally used to the advantage of patients in daily clinical practice. We postulate that more insight in the patients* daily lifestyle behaviour provides crucial information that can be used to improve patient selection for cardiac interventions. In addition, objective and subjective monitoring can be used to personalize lifestyle interventions, leading to improvements of in-hospital and long-term outpatient clinical care, as well as better self-motivation, quality of life and health status.

Adherence to continuously providing self-tracking data via automatically monitoring technologies is key. Without data provided by the patients, personalized and improved treatment decisions cannot be made. However, there is a gap in literature regarding the adherence to continuous lifestyle monitoring technologies for a longer period of time. Whereas previous research showed high levels of adherence associated with monitoring technology, these studies focused on relatively short programs. Secondly, studies typically focus on monitoring only one lifestyle domain rather than a combination. Yet, the use of monitoring technology to improve fitness and wellbeing is a clear trend and may potentially be particularly useful as assistive tool to stimulate healthy lifestyle in special population. Therefore, there is a clear need for further research in evaluation of the adherence and usability of this kind of digital health technology in CVD care and management.

This project aims to develop and evaluate the adherence and usability of a system that integrates innovative methods for continuous unobtrusive and patient-friendly monitoring of lifestyle factors (i.e. daily physical activity levels, dietary habits, mental stress and sleep quality) in patients with coronary artery disease (i.e. patients selected for coronary artery bypass surgery (CABG), radiofrequency catheter ablation (RFCA), a transcathethr aortic valve implantation (TAVI), or valve surgery). These patient groups are selected because the diseases are common, treatment decisions are often complex, and

technically and medically successful treatments are often not accompanied by optimal changes in lifestyle factors. A system that aids patients in monitoring their lifestyle factors will enable better self-management and improve self-motivation, with subsequent positive effects on the lifestyle factors themselves. Therefore, this study will investigate adherence to self-monitoring lifestyle with a novel integrated lifestyle monitoring system.

Study objective

The primary objective of this project is to assess the adherence to a patient-centred integrated lifestyle monitoring system that tracks daily physical activity levels, dietary habits, mental stress and sleep quality.

Study design

This is a prospective observational trial.

Study burden and risks

No risks are associated with participation in the present study. An activity tracker will be worn 2 weeks per month for a one-year period to collect data on activity behaviour (step count, accelerometer counts and heart rate) and sleep duration. Subjective data will on nutritional intake, mental stress and sleep quality will be acquired via questionnaires and a chatbot connected to a patient monitoring system accessible via mobile phone, tablet and desktop. Patient-reported outcomes will be obtained using standard questionnaires at three-months intervals. Patients will have insight in their lifestyle data but will not receive treatment or coaching based upon these parameters (caretakers do not have access to the platform) as this project is focused on a patient-centred monitoring approach.

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 selected for or that underwent coronary artery bypass surgery (CABG), an electrophysiological test (EFO) and/orradiofrequency catheter ablation (RFCA), a transcatheter aortic valve implantation (TAVI), a fractional flow reservetest (FFR) and/or a percutaneous coronary intervention (PCI), and/or valve surgery.
- Age >= 18 years.
- Able to speak and read the Dutch language.
- Willing and able to provide informed consent.

Exclusion criteria

- No internet connection at home.
- Not in possession of a computer or tablet, and mobile phone.
- Not able or willing to wear activity tracker on a daily basis (for example due to work related obligations).
- Major planned (cardiac) surgery in the upcoming 3 months.
- Life expectancy < 1 year (e.g., severe renal disease, metastatic cancer).
- Physical impairments interfering with the lifestyle monitoring system, including not able to perform daily physical activities due to orthopaedic or neurological disease, bed/chair ridden patients, visual impairments/blindness, sever cognitive disability.
- Presence of wounds, injuries or infectious diseases on the skin where the wrist-wearable device(s) will be placed.
- Refusal to informed consent.

- Mentally incompetent.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	08-11-2021
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	08-10-2021
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 20607

Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL78062.015.21
OMON	NL-OMON20607