Adherence to a Lifestyle Monitoring System in Patients with Heart Disease

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON20607

Source
Nationaal Trial Register

Brief title
Care-On

Health condition

Coronary artery disease (CAD)
Atrial fibrillation (AF)

Sponsors and support

Primary sponsor: Máxima Medisch Centrum, Dominee Theodor Fliednerstraat 1, 5631 BM Eindhoven, The Netherlands
Source(s) of monetary or material Support: Máxima Medisch Centrum, Dominee Theodor Fliednerstraat 1, 5631 BM Eindhoven, The Netherlands

Intervention

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 sharingfunctionality 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 monitoringsystem 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, dietaryhabits, mental stress, sleep quality and smoking habit, are strongly related to the occurrence, clinical course and overall treatmentoutcomes 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 onthe clinical course of patients with coronary artery disease and atrial fibrillation. However, despite their undisputed relevance, theselifestyle factors are currently not objectively and subjectively monitored and therefore not optimally used to the advantage of patientsin daily clinical practice. We postulate that more insight in the patients' daily lifestyle behaviour provides crucial information that canbe used to improve patient selection for cardiac interventions. In addition, objective and subjective monitoring can be used topersonalize 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 thepatients, personalized and improved treatment decisions cannot be made. However, there is a gap in literature regarding theadherence to continuous lifestyle monitoring technologies for a longer period of time. Whereas previous research showed high levelsof adherence associated with monitoring technology, these studies focused on relatively short programs. Secondly, studies typicallyfocus on monitoring only one lifestyle domain rather than a combination. Yet, the use of monitoring technology to improve fitness andwellbeing is a clear trend and may potentially be particularly useful as assistive tool to stimulate healthy lifestyle in specialpopulation. Therefore, there is a clear need for further research in evaluation of the adherence and usability of this kind of digitalhealth 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 continuousunobtrusive and patient-friendly monitoring of lifestyle factors (i.e. daily physical activity levels, dietary habits, mental stress andsleep quality) in patients with coronary artery disease (i.e. patients selected for coronary artery bypass surgery (CABG), a cardiacelectrophysiology test (EFO) and/or catheterization, a transcathethr aortic valve implantation (TAVI), or valve surgery). These patientgroups are selected because the diseases are common, treatment decisions are often complex, and technically and medicallysuccessful treatments are often not accompanied by optimal changes in lifestyle factors. A system that aids patients in monitoringtheir lifestyle factors will enable better self-management and improve self-motivation, with subsequent positive effects on the lifestylefactors themselves. Therefore, this study will investigate adherence to self-monitoring lifestyle with a novel integrated lifestylemonitoring system.

Study objective

A drop-out rate of 50% at 1 year follow up is anticipated.

Study design

Inclusion: (one week) before cardiac intervention in the hospital.
Start of monitoring year: from intervention in hospital onwards.

Contacts

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Eligibility criteria

Inclusion criteria

- Patients selected for coronary artery bypass surgery (CABG), a cardiac electrophysiology test (EFO) and/orcatheterization, a transcathethr aortic valve implantation (TAVI), 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, tablet or 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 physicalactivities 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 beplaced
- Refusal to informed consent
- Mentally incompetent

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	07-11-2021
Enrollment:	100
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	06-11-2021
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 50694
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL9861
CCMO	NL78062.015.21
OMON	NL-OMON50694

Study results