Adherence to a Lifestyle Monitoring System in Patients with Heart Disease

Gepubliceerd: 06-11-2021 Laatst bijgewerkt: 19-03-2025

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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON20607

Bron
Nationaal Trial Register

Verkorte titel
Care-On

Aandoening

Coronary artery disease (CAD)
Atrial fibrillation (AF)

Ondersteuning

Primaire sponsor: Máxima Medisch Centrum, Dominee Theodor Fliednerstraat 1, 5631 BM Eindhoven, The Netherlands
Overige ondersteuning: Máxima Medisch Centrum, Dominee Theodor Fliednerstraat 1, 5631 BM Eindhoven, The Netherlands

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary endpoint is the adherence (i.e., the % of participants still using a patient-centred

lifestyle monitoring system at 1-year follow-up).

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Contactpersonen

Publiek

Máxima MC
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040-8888220

Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	07-11-2021
Aantal proefpersonen:	100
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	06-11-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 50694
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten