Pattern recognition in heart rate variability using fitness trackers in cardiovascular diseases.

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The primary objective of this study is to detect HRV patterns which are related to cardiovasculair disease such as permanent atrial fibrillation or (congestive) heart failure using a wearable fitness tracker.

Ethical review	Approved WMO
Status	Completed
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON53999

Source
ToetsingOnline

Brief title
Pattern recognition in cardiovascular diseases.

Condition

- Other condition
- Cardiac arrhythmias

Synonym
atrial fibrillation, heart failure

Health condition

kunstmatige intelligentie

Research involving
Human

Sponsors and support

Primary sponsor: HagaZiekenhuis
Source(s) of monetary or material Support: Innovatiegelden van vakgroep Cardiologie Haga zullen promotie financieren aangevuld met subsidies welke nog aangevraagd moeten worden (National Health Service;ZonMW;Interuniversity Cardiology Institute of the Netherlands;etc)

Intervention

Keyword: Cardiovascular diseases, Fitness trackers, Heart rate variability, Pattern recognition

Outcome measures

Primary outcome

The primary objective of this study is to detect HRV patterns which are related

to cardiovas-cular disease such as permanent atrial fibrillation or

(congestive) heart failure using a weara-ble fitness tracker.

Secondary outcome

- Quantify study participant compliance rate of wearable fitness tracker

Study description

Background summary

Heart rate variability (HRV) is a non-invasive parameter which indicates the variation in the heartrate within a timeframe. HRV provides a measure of how study subjects react and adapt to stress, physical fatigue and metabolic-request changes and disease. Several other studies have shown that HRV is a prognostic indicator of arrhythmic events and mortality in study participants experiencing following a myocardial infarction and in congestive heart fail-ure study participants. In study participants with heart failure, reduced or abnormal HRV are indicators of an increased risk of mortality. Wearable fitness trackers, such as the FitBit, are non-invasive tools that can easily monitor the HRV of study participants in an outstudy participant setting using a photoplethysmo-graphic (PPG) sensor.
The recognition of a unique HRV pattern using AI in cardiovascular diseases could be clinically relevant when realizing early detection of cardiovascular

events, without submitting study participant in the hospital to potential invasive and burdensome tests.
With the help of machine learning, we hypothesize that for each respective cardiovascular disease, such as permanent atrial fibrillation and systolic heart failure, a unique HRV based pattern can be found.

Study objective

The primary objective of this study is to detect HRV patterns which are related to cardiovasculair disease such as permanent atrial fibrillation or (congestive) heart failure using a wearable fitness tracker.

Study design

Single-center observational feasibility cohort trial performed in the Haga Teaching Hospital in The Hague, The Netherlands.

Study burden and risks

None

Contacts

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Scientific
HagaZiekenhuis

Els Borst-Eilersplein 275
Den Haag 2545AA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
- Study participants who are 18 years or older.
Group 1: Study participants who are diagnosed with permanent atrial fibrillation.
Group 2: Study participants with systolic heart failure (LVEF < 35%) with an implantable car-diac device without documented atrial fibrillation.
Group 3: Healthy individuals, with a normal electrocardiogram

Exclusion criteria

A potential study subject who meets any of the following criteria will be excluded from participation in this study:
- paroxysmal or persistent atrial fibrillation
- Elderly study participants > 85 years old
- Recent pulmonary venous antrum isolation (PVAI) procedure (< 1 year)
- (end stage) Kidney failure
- (end stage) Liver failure
- Study participants with a history of cardiothoracic surgery
- Study participants with a history of multiple myocardial infarction
- Study participants with known systemic active inflammatory disease
- Study participants with impaired mental state
- Alternation in rhythm medication (Monthly)
- Inability to use a fitness tracker or mobile phone
- Impaired cognition and inability to understand the study protocol
- Study subject with known metastatic disease

Study design

Design

Study type:	Observational non invasive

Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	24-05-2022
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO

Date:	23-09-2021
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	15-04-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	03-03-2023
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	21-04-2023

Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL73708.058.20