The MyHeart Counts cardiovascular Health Study Netherlands

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Cardiac disorders, signs and symptoms NEC
Study type	Interventional

Summary

ID

NL-OMON52971

Source
ToetsingOnline

Brief title
MyHeart Counts NL

Condition

- Cardiac disorders, signs and symptoms NEC
- Lifestyle issues

Synonym
cardiovascular disease; lifestyle

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: NFU Citrien eHealth fonds,Zorg & Zekerheid (zorgverzekeraar)

Intervention

Keyword: cardiovascular health, eHealth, feasibility, observational study

Outcome measures

Primary outcome

effectiveness (mean step counts per day) of four coaching interventions

Secondary outcome

Feasibility (technical, legal and ethical, data quality, costs)

Diet, Smoking, Well-being, Risk perception of cardiovascular disease, Physical

activity, Sleep and self-reported cardiovascular disease.

Study description

Background summary

The study of determinants of cardiovascular disease (CVD) is important because it provides insight in risks and opportunities to reduce the burden of CVD. A major gap in our current knowledge about CVD lies in the way we measure these determinants, for example physical activity. This is currently restricted to paper questionnaires and short-duration measurements. Here lies the potential for smartphone technology. The ResearchKit MyHeart Counts app allows researchers to collect data continuously and in large populations. Addutionally, in-app coaching could stimulate a healthy lifestyle. However, the effect of different coaching levels on a smartphone is not yet known. The MyHeart Counts app has been released successfully in the USA by Stanford University. However, the effect and feasibility of this method for use in the Netherlands has not been established.

Study objective

The primary aim is to assess the effectiveness of four coaching interventions in increasing daily activity of MyHeart Counts app users.

Secondary aims are 1) to study the feasibility (technical, legal and ethical, data quality, costs) of the MyHeart Counts app in the Dutch ambulatory population 2) to study the associations of determinants (Diet, Smoking, Well-being, Risk perception of cardiovascular disease, Physical activity,

Sleep) of cardiovascular disease with self-reported cardiovascular health and 3) Subgroup analysis of primary endpoint. Test whether a particular cluster of individuals will respond more or less favourably to a particular prompt.

Study design

app-based observational study with integrated cross-over trial

Intervention

four different coaching levels

Study burden and risks

The observational study consists of 7-day study periods, with a frequency of one study period per three months. During these study periods participants will be asked to answer in-app questionnaires and perform a 6-minute walk test with their smartphone at the end of the week. After the first study period, participants are randomized to four different coaching levels in four subsequent weeks. In total, the study takes 5-10 minutes per day in the first week, and 1-2 minutes per day in the following four weeks. The total study takes 5 weeks. Participating with this research does not carry extra health risks. Benefits for participants include getting insight in their cardiovascular risk, personal lifestyle coaching and easy contribution to cardiovascular research from their smartphone.

Contacts

Public
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2300RC
NL
Scientific
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2300RC
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:, - >=18 years
- Living in the Netherlands
- Own an iPhone 5s or higher with the latest software (at least iOS 8)

Exclusion criteria

All participants not meeting the inclusion criteria are not allowed to entry the study.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-10-2022
Enrollment:	1213
Type:	Actual

Ethics review

Approved WMO Date:	18-04-2019
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	29-08-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	11-05-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	23-12-2022
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

ID: 20977
Source: NTR
Title:

In other registers

Register	ID
Other	7429
CCMO	NL61951.058.18
OMON	NL-OMON20977