De Mijn Hart Telt studie: onderzoek naar hart- en vaatziekten in Nederland

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20977

Source
Nationaal Trial Register

Brief title
Mijn Hart Telt

Health condition

Cardiovascular disease
eHealth
Observational study
Feasibility
Hart- en vaatziekten
eHealth
Observationeel onderzoek
Haalbaarheid
Smartphone

Sponsors and support

Primary sponsor: Leiden University Medical Centre (LUMC)
Source(s) of monetary or material Support: Citrienfonds NFU; Netherlands eHealth Living Lab (NeLL)

Intervention

Outcome measures

Primary outcome

Study the effectiveness of four coaching interventions in increasing daily activity of MyHeart Counts app users.

Secondary outcome

- Study the feasibility (technical, legal and ethical, data quality, costs) of the MyHeart Counts app in the Dutch ambulatory population.

- Study the association of determinants (Diet, Smoking, Well-being, Risk perception of cardiovascular disease, Physical activity, Sleep) of cardiovascular disease with self-reported cardiovascular health.

- Subgroup analysis of primary endpoint. Test whether a particular cluster of individuals will respond more or less favourably to a particular prompt.

Study description

Background summary

This is an app-based randomized intervention study in The Netherlands, studying the effectiveness of four smartphone coaching interventions in increasing daily activity. The app has been succesfully released by Stanford University, USA, however, the effect and feasibility of the app for use in The Netherlands has not been established yet. We will therefore also be performing a feasibility study. As well as that, we aim to study the association between determinants of cardiovascular disease (CVD) with self-reported cardiovascular health. Everybody in The Netherlands aged 18 and older is invited to join to MyHeart Counts.

Study objective

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. Additionally, 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. The effect and feasibility of this method for use in the Netherlands has not been established.

Study design

June 2018 - May 2021: study preparations, e.g. establishing electronic informed consent procedure, build a safe and legally adequate data exchange infrastructure, tailor app code to Dutch situation, implement Dutch cardiovasculair risk tool, etc.
May 2021: App launch, start of study

Intervention

Different coaching promts (iPhone notifications)

Contacts

Public
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The Netherlands
071-5268444
Scientific
LUMC
A.V. Silven
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Eligibility criteria

Inclusion criteria

Participants should be:

- Aged 18 years or older

- Living in the Netherlands

- Own an iPhone 5s or higher with the latest software (at least iOS8)

Exclusion criteria

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

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2021
Enrollment:	1200
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	13-08-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 52971
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7230
NTR-old	NTR7429
CCMO	NL61951.058.18
OMON	NL-OMON52971

Study results