

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

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Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20977

Bron

Nationaal Trial Register

Verkorte titel

Mijn Hart Telt

Aandoening

Cardiovascular disease

eHealth

Observational study

Feasibility

Hart- en vaatziekten

eHealth

Observationeel onderzoek

Haalbaarheid

Smartphone

Ondersteuning

Primaire sponsor: Leiden University Medical Centre (LUMC)

Overige ondersteuning: Citrienfonds NFU; Netherlands eHealth Living Lab (NeLL)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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 successfully 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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

Contactpersonen

Publiek

LUMC
A.V. Silven
Leiden
The Netherlands
071-5268444

Wetenschappelijk

LUMC
A.V. Silven
Leiden
The Netherlands
071-5268444

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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)

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-05-2021
Aantal proefpersonen:	1200
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:	13-08-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 52971
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten