mHealth in grown-ups congenital heart disease

No registrations found.

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

Summary

ID

NL-OMON27137

Source
Nationaal Trial Register

Brief title
mHealth GUCH

Health condition

Any congenital heart disease

Sponsors and support

Primary sponsor: Amsterdam UMC, location AMC, Netherlands Heart Intitute
Source(s) of monetary or material Support: Dekkerbeurs NHI

Intervention

Outcome measures

Primary outcome

Less unplanned contact moments in the hospital

Secondary outcome

Earlier treatment (medication or hospitalization), reduce healthcare costs, increased patient

statisfaction

Study description

Background summary

usage of HartWacht (telemonitoring) in patients with a congenital heart disease to determine if telemonitoring reduces the number of unplanned hospital visits. Half of the patients receive their normal care, the other half receives a single lead EKG, blood pressure monitor and a scale. Patients measure blood pressure and weight twice a week and make an EKG once a month. When feeling bad, the patient can make extra recordings. Feedback will be given to every recording. After two years the number of unplanned hospital visits, number of calls to the hospital / cardiologist, and the number of presentations on the ER will be compared between the two groups. Besides looking at the number of contact moments between hospital and patient, we will also assess the quality of live by means of the EuroQoL-5D-5L, SF-36, and the PAM-13 questionnaires.

Study objective

mHealth will reduce the number of unplanned contact moments with the hospital / cardiologist

Study design

every 3 months

Intervention

mHealth apparatus like single lead EKG, blood pressure apparatus and body weight scale

Contacts

Public
Amsterdam UMC, locatie AMC
Marinka Oudkerk Pool

0205668679
Scientific
Amsterdam UMC, locatie AMC
Marinka Oudkerk Pool

0205668679

Eligibility criteria

Inclusion criteria

Symptoms of palpitation, arrhythmia. At least three extra contact moments with the hospital, next to the regular scheduled contact moment with the cardiologist. Over age 18. Congenital heart disease patient as identified through the CONCOR database

Exclusion criteria

Mentally disabled, tremor, within 6 months of cardiac surgery, ablation or other invasive cardiac procedure, not in possession of smartphone or personal computer.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	08-05-2019
Enrollment:	196
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	04-06-2019
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 49010
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL8006
CCMO	NL68384.018.18
OMON	NL-OMON49010

Study results