mHealth in Grown-up Congenital Heart Disease

Published: 23-01-2019
Last updated: 15-05-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Congenital cardiac disorders
Study type	Interventional

Summary

ID

NL-OMON49010

Source
ToetsingOnline

Brief title
eGUCH

Condition

- Congenital cardiac disorders
- Cardiac and vascular disorders congenital

Synonym
Congenital heart disease, symptomatic

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Nederlandse hartstichting

Intervention

Keyword: Congenital heart disease, eHealth, mHealth, Telemonitoring

Outcome measures

Primary outcome

The primary research question is to assess the effect of mHealth-based monitoring on the number of contact moments with the hospital (i.e. contact with the outpatient clinic (visits and telephone consults), visits to the emergency department, and hospitalizations), in comparison with the control group.

Secondary outcome

Secondary research questions are superiority of health-related quality of life, as measured with the EuroQol-5D-5L, SF-36 and PAM-13 using the mHealth intervention in comparison with the control group and the number of contact moments, outpatient clinic visits, ER visits and emergency admissions. Research questions on cost effectiveness are whether a mHealth-based monitoring pathway leads to cost reduction through change in the number of contact moments with the hospital (i.e. contact with the outpatient clinic (visits and telephone consults), visits to the emergency department, and hospitalizations), in comparison with the control group.

Study description

Background summary

mHealth, the provision of targeted medical care through mobile technologies, is expected to drastically change traditional health structures and is reputed to

be cost-effective. The growing and aging congenital heart disease (CHD) population, seems especially prone to benefit from mHealth, as they are young and lifelong affected by their heart disease. So far, there is little evidence on the effectiveness of mHealth in GUCH patients, and only minor pilot data in patients with other chronic diseases are available. This lack of evidence, particularly in the GUCH population, is the reason for our current proposal for a first research on clinical- and costeffectiveness of mHealth telemonitoring.

Study objective

The aim of the proposed randomized controlled trial (RCT) is to determine the effectiveness, and related healthcare costs of a mHealth-based targeted clinical monitoring pathway in GUCH patients. The primary research question is to assess the effect of mHealth-based monitoring on the number of contact moments with the hospital (i.e. contact with the outpatient clinic (visits and telephone consults), visits to the emergency department, and hospitalizations), in comparison with the control group. Secondary research questions are superiority of health-related quality of life, as measured with the EuroQol-5D-5L, SF-36 and PAM-13 using the mHealth intervention in comparison with the control group and the number of contact moments, outpatient clinic visits, ER visits and emergency admissions. Research questions on cost effectiveness are whether a mHealth-based monitoring pathway leads to cost reduction through change in the number of contact moments with the hospital (i.e. contact with the outpatient clinic (visits and telephone consults), visits to the emergency department, and hospitalizations), in comparison with the control group.

Study design

The proposed study is a multi-centre, parallel, two-groups, open, randomized controlled trial in symptomatic (e.g. cardiac arrhythmias, congestive heart failure) GUCH patients.

Intervention

Patients in the intervention group will be monitored for 24 months. The mHealth telemonitoring program will be used in addition to usual care. The mHealth telemonitoring program will monitor body weight, blood pressure, heart rate and single lead EKG. Patients in the intervention group will receive three wireless devices at home to perform measurements. The results of the measurements can be sent through smartphone applications or via computer (website). Patients are expected to perform weight, blood pressure and heart rate measurements twice every week on weekdays. Once every month patients are expected to perform a single lead EKG. The research fellow will contact the patients to assist the patient with installing the devices and performing the first measurements. Patients can perform extra measurements in case of symptoms. Measurements will

be analyzed daily by the research fellow. Patients will be contacted in case of multiple threshold exceeding measurements. The treating physician will be consulted if needed.

Study burden and risks

Patients are expected to perform weight, blood pressure and heart rate measurements twice every week on weekdays. Once every month patients are expected to perform a single lead EKG. Patients are requested to fill in quality of life questionnaires every three months. The risk is negligible.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

> 18 years
Congenital heart disease patient
Symptomatic in the last 1 year: Heart failure NYHA class * II, palpitations or arrhythmias, hypertension.
Patients with a genetic abnormality resulting in an altered cardiac anatomy or function.

Exclusion criteria

Unable to give informed consent
Tremor
Not in possession of smart phone or personal computer

Study design

Design

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

Primary purpose: Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-05-2019
Enrollment:	196
Type:	Actual

Medical products/devices used

Generic name:	1-lead ECG (Kardia) and blood pressure measurement (iHealth)
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	23-01-2019
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-07-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-09-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-10-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-03-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-05-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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: 27137
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL68384.018.18
OMON	NL-OMON27137