The Box: using smart technology to improve one-year outcome of myocardial infarction patients

Published: 10-05-2016
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The objective of this study is to measure the effect of a smart technology intervention on patients after AMI.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Coronary artery disorders
Study type	Interventional

Summary

ID

NL-OMON43527

Source
ToetsingOnline

Brief title
The Box

Condition

- Coronary artery disorders

Synonym
heart attack, Myocardial infarction

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: e-Health, Myocardial infarction, Smart technology

Outcome measures

Primary outcome

The primary endpoint of the study will be the percentage of patients with

controlled blood pressure in both groups.

Secondary outcome

• Scores of SFQ-questionnaires

• Hospital-patient contact

• Amount of hospital visits

• Scores of Rand-36 questionnaires

• Major Adverse Cardiac Events

• Time between discharge from hospital and completion of device installation

• Cost-effectiveness of interventions in both groups

• Scores of medication-adherence questionnaires

Study description

Background summary

Smart technology could improve quality of care in patients after acute myocardial infarction (AMI) with either ST or non-ST elevation.

Study objective

The objective of this study is to measure the effect of a smart technology intervention on patients after AMI.

Study design

The design of the study is a single-center, open randomized-controlled trial.

Intervention

Patients will be randomized to either *The Box* or regular follow-up. Patients who have been randomized to The Box will receive a box containing a smartphone compatible ECG monitor, a weight scale, an activity tracker and a blood pressure monitor. If patients are randomized to The Box, two of the four outpatient clinic visits will be replaced by an e-consult, in which a patient does not have to go to the hospital, but talks with his or her doctor or nurse practitioner via a secured video connection.

Study burden and risks

All devices used in this study are non-invasive, easy-to-use and electrically safe within its intended use. Using the devices is with very limited risks. This study has some potential benefits for patients: first, patients can measure their own blood pressure, weight and activity, as well as record their own ECG. This can reassure patients and give them more insight in their own health (the so-called *patient empowerment*). Furthermore, more data gives the doctor more insight in the health of patients. This might lead to early detection of hypertension or arrhythmias such as atrial fibrillation. Lastly, due to the video connection system, patients do not have to come to the hospital, while receiving the same quality of care. A drawback is that patients have to measure their blood pressure, weight and ECG every day. Furthermore, patients have to fill in a couple of questionnaires, which will take some of their time.

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

1. Myocardial infarction (either ST or NST elevation)
2. Patient is able to communicate in English or Dutch language
3. Patient is familiar with smartphone technology

Exclusion criteria

1. Body Mass Index > 35 kg•m-2
2. Patient is included in another randomized controlled trial
3. Patient is <18 years old
4. Patient is considered an incapacitated adult
5. Patient is pregnant

Study design

Design

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

Primary purpose: Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-05-2016
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO Date:	10-05-2016
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
Approved WMO Date:	30-03-2017
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL56453.058.16

Study results

Date completed:	14-12-2018
Actual enrolment:	200

Summary results
Trial is onging in other countries