ACS Prototype for 'post-discharge self-management'- proposition for patients, medical staff and care institution.

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To gain qualitative insights into the value of the *ACS post-discharge self-management proposition* for patients, medical staff and care institution. Understand how this prototype is used in practice by patients and staff * Investigate how it...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Coronary artery disorders
Study type	Observational non invasive

Summary

ID

NL-OMON44439

Source
ToetsingOnline

Brief title
Alkmaar ACS Prototype Test

Condition

- Coronary artery disorders

Synonym
post-infarction self management

Research involving
Human

Sponsors and support

Primary sponsor: Philips Research
Source(s) of monetary or material Support: Philips-NWZ samenwerking

Intervention

Keyword: ACS, Disease management, Infarct, PCI

Outcome measures

Primary outcome

Patients:

* Understanding of care process & own condition

* Self-efficacy; knowledge, skills and confidence in the management of their own health

* Patient activation and self initiative

* Communication with professionals

* Role of the overal proposition or its specific functionalites to influence satisfaction with care

* Motivation and potential willingness to pay for this proposition

Staff:

* Consults (clinical decision making/ treatment advice, coaching, titration and med. management)

* Workflow (communication, education, scheduling)

* Patient engagement (compliance, self-efficacy, clinical situation ..)

* Staff satisfaction

Secondary outcome

nvt

Study description

Background summary

Patients who have been discharged from hospital after being treated for a heart attack (intervention, bypass) typically receive a program of care that includes medication therapy and rehabilition. Patients also receive an information package at discharge about their condition and details on how to manage their condition (and symptoms) during and after their care plan. Health care providers (cardiologists, nurse specialists, rehab nurses) are currently dissatisfied with patient self management support because many patients drop out of rehabilitation and their lifestyle reverts to pre-event patterns after the rehabilition support. Patients often complain about being overloaded with information directly post-discharge while lacking support at later moments in their recovery. Hospitals (such as Alkmaar) are interested to work with manufacturers and solution providers to give connected tools to their patients to measure and manage their recovery. The ACS prototype is designed to support these different stages of recovery to allow the patient to better self manage and contextualize their condition (symptoms, heart rate, blood pressure, weight) in relation to their activity and medication and helps them to better communicate with their care provider. The ACS prototype also provides information to the care provider about the status and concerns of their patients during the consultations and between consults. Currently there is no solution on the market that offers such a complete package for patients.

Study objective

To gain qualitative insights into the value of the *ACS post-discharge self-management proposition* for patients, medical staff and care institution.
Understand how this prototype is used in practice by patients and staff *
Investigate how it affects the self management and clinical workflow for ACS post-discharge patients.
Gather feedback on overall prototype, and independent functionalities/features for future development and scaling of the prototype.

Study design

This prototype test will be an explorative evaluation.

The patients will be recruited before the moment of discharge from the NWZ hospital (after they had a cardiac intervention), and will test the prototype for a period of 5 weeks. During this period, 2-3 weeks of rehabilitation is provided by the rehab nurses as part of the standard post-discharge care program as well as a cardiopulmonary exercise test to determine the patient*s exercise capacity (again part of the standard procedure of the hospital). The

prototype consists of a prototype app installed on an iPhone, combined with the connected healthwatch, bloodpressure cuff and weighing scale.
App usage data will be collected via automated tracking. Additional qualitative data will be obtained through interviews with the patients at three points in time: at the moment of intake/onboarding, after week 1, and at the end of their participation after week 5. Patients will also receive a weekly short (digital) questionnaire to share their immediate feedback / evaluation of the prototype.
Throughout the total duration of the study (3 months), also a selected group of Healthcare professionals (HCPs) will participate in the study and use the professional interface of the prototype app. Before the start of the study they will receive a training and instructions for use, and halfway and at the end of the study, focus group sessions will take place to gather to collect their feedback / evaluation of the prototype.

Study burden and risks

Patients will wear a smart-watch watch connected to an i-phone for 5 weeks. The watch contains a number of instruments that can measure heart rate and exercise performances.
In addition, the patient receives an electronic weight scale and an electronic blood pressure monitor. On request the patient is asked to measure the weight once a day and measure the blood pressure a few times.

The application is installed on the phone and has a number of characteristics:
Displaying the measurements,
Ability to register and display complaints,
Chat function that can be used on the initiative of the patient
Video function that can be used on the initiative of the patient
A messaging feature that sends daily personalized messages to the patient; focused on information and education

The potential negative burden is in terms of time load 90 minutes in 5 weeks predominantly at the initiation and exit visits
The patient is asked to perform a few measurements daily

Contacts

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Scientific

Philips Research

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

post-discharge infarction patients

Exclusion criteria

heart-failure
not being able to use mobile devices
electronic implants

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	14-07-2017
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	29-06-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-09-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	10-11-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-12-2017
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

No registrations found.

In other registers

Register	ID
CCMO	NL61780.094.17