Telemonitoring of congestive heart failure patients through a personal health system - technological feasibility study

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Ethical review	Approved WMO
Status	Pending
Health condition type	Heart failures
Study type	Observational non invasive

Summary

ID

NL-OMON31880

Source
ToetsingOnline

Brief title
Technological feasibility of telemonitoring in heart failure patients

Condition

- Heart failures

Synonym
monitoring heart failure

Research involving
Human

Sponsors and support

Primary sponsor: Intel Corporation

Source(s) of monetary or material Support: Intel Inc. ;Digital Health Group

Intervention

Keyword: heart failure, technology, telemonitoring

Outcome measures

Primary outcome

1. What was the patient*s satisfaction rating (incl. confidence in PHS) of their PHS experience ?

2. What was the nurse*s satisfaction rating of their PHS experience ?

3. What was the GP/Specialist*s satisfaction rating of their PHS experience ?

4. What was the average time spent per service center nurse per month ?

5. What percentage of the equipment malfunctioned ?

6. What was the patient*s adherence rate to the PHS (incl number of patients refusing to participate) ?

7. What was the average length of time from monitoring to nurse call-back ?

Secondary outcome

1 Blood Pressure Control. Evaluation of the change and variation of daily BP measurements taken over a 3/6 month period of time.

2. Weight Control. Evaluation of the change and variation of daily weight measurements taken over a 3 month period of time.

3. Blood Oxygen Saturation Control. Evaluation of the change and variation of daily blood oxygen saturation measurements taken over a 3 month period of time.

4. Qualitative data (observations, anecdotes, patient comments, etc.) on the installation, training, patient/caregiver/clinician/technician experience, etc.

Study description

Background summary

Telemonitoring for patients with stable Congestive Heart Failure my improve the patient's span of control and patient compliance to monitoring. It also improves cost-efficacy of the application of medical and nursing care.

Study objective

The proposed study aims to assess the technical reliability and user friendliness of the Intel platform in 25 patients who are in stable heart failure. Subsequently, the cost-efficacy of the technology will be assessed in 100 patients with a focus on process and system analysis. In this phase also the effect of teleconsulting will be subject of study.

Study design

The subject of the study is the use of the Intel Personal Health System. The system consist of a reinforced laptop connected to ADSL. Via the Laptop blood pressure, weight, and oxygen saturation are measured according to a preset data acquisition protocol. The study is an observational prospective study with assess the measurements. The measurement tools for bloodpressure, weight and oxygen saturation are already in use on a large scale and appeared reliable. In both fases of the study data are registered and stored in a personal patient dossier within a specially operated study database. The data collection period for the first phase is 3 months. In the second part of the study video-conferencing and teleconsulting will be available. Another 100 patients enrolled in three non-university hospital heart failure clinics will be invited to participate.

Study burden and risks

Participant*s identity shall be known only to the researchers / technicians who visit the participant*s home to install equipment or perform testing. All participant coded data shall be kept in password protected computers or locked file drawers. Personal health information shall not be allowed to be a part of any data leaving AMC and/or Intel/IPT. Privacy and security risks will also be outlined in the patient informed consent document.

The overall risk of this observational and subjective study is considered very low (Minimal risk category). Participation in the study doesn*t interfere with the regular controls by the nursing or medical staff. In this study, patients suffer from congestive heart failure but are in a steady control state that doesn*t require intensive monitoring.

The Intel® Personal Health System is CE marked for this study in the Netherlands. Therefore, safety and applicable regulatory compliance shall be met prior to the medical device being deployed in hospitals and homes.

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

Patients with congestive heart failure in a stable condition wether or not post-surgery, treated by a cardiologist.
Patients must be capable of handling the computer and the monitoring equipment
Patients must understand the instructions by nurse and doctor

Exclusion criteria

Progressive heart failure.
No ADSL or insufficient knowledge of English (according to a simple language test)
Serious co-morbidity and end-stage disease of any kind
Mental shortcomings

Study design

Design

Study phase:	4
Study type:	Observational non invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-06-2008
Enrollment:	25
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
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	NL23264.018.08