Pilot study to test usability of wearable biosensor in elderly with non-specific complaints

Gepubliceerd: 21-07-2016 Laatst bijgewerkt: 13-12-2022

Ethische beoordeling	Niet van toepassing
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20672

Bron
NTR

Aandoening

elderly with non-specific complaints

Ondersteuning

Primaire sponsor: Philips Research
Overige ondersteuning: Sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

To assess the successful usage of the wearable biosensor with the smartphone app (i.e. patient feedback, caregiver feedback, raw device data, technical operational data),

Toelichting onderzoek

Achtergrond van het onderzoek

This study is designed to investigate the efficacy of wearable monitoring devices for elderly NSC-patients in 2 different use case scenarios. Use case 1 (patients in the pre-hospital setting), Use case 2 (patients discharged home from the ED or hospital). Each patient will wear a biosensor (on the chest) connected to an app (a smartphone is running the app) for a certain period of time as defined by the clinical investigation plan – the biosensor will measure vital signs and biometric signals. At the end of the study period, the patients will be asked some questions related to usability of the wearable biosensor with the smartphone app.

Onderzoeksopzet

30 days

Onderzoeksproduct en/of interventie

The participants will wear a wearable biosensor that will record the vital parameters continuously

Contactpersonen

Publiek

Philips Research Eindhoven
Celine Reverseau
High Tech Campus 34
Eindhoven 5656 AE
The Netherlands
m:+31-6-31639778

Wetenschappelijk

Philips Research Eindhoven
Celine Reverseau
High Tech Campus 34
Eindhoven 5656 AE
The Netherlands
m:+31-6-31639778

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Group 1: Optimal triage in the pre-hospital setting

• Age ≥ 65 years;

• Patient at the GP’s office with non-specific complaint(s) only;

• Patient living in a home residence with/without home care or home residence;

• ISAR score ≥ 2;

• Informed consent.

Group 2: Follow-up of discharged patients from the internal medicine ward/ED.

• Age ≥ 65 years;

• Registered at the ED for Internal Medicine or patients will be discharged from the hospital;

• Patients do not present with specific complaints;

• Patients are ready for discharge home;

• Patients living at home (with/without home care) or home residence;

• ISAR ≥3;

• Informed consent.

Group 3: Control

• Age ≥ 65 years;

• Informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Group 1: Optimal triage in the pre-hospital setting

• Patients with positive anamnesis and/or medical examination for specific complaints;

• Age < 65 year;

• Patients with life expectancy <3 months (terminally ill patients);

• ISAR score <2.

• Patients who have implanted defibrillators or pacemakers

• Damaged or very vulnerable skin around patch location

• Allergic to silicone or hydrocolloid adhesive materials

Group 2: Follow-up of discharged patients from the internal medicine ward/ED.

• Age < 65 years;

• Other specialties besides internal medicine;

• Patients with diagnosed dementia;

• Patients living in a nursing home;

• Patients with an active oncologic disease;

• Patients with a live expectancy of less than 3 months;

• ISAR <3 score.

• Patients who have implanted defibrillators or pacemakers

• Damaged or very vulnerable skin around patch location

• Allergic to silicone or hydrocolloid adhesive materials

Group 3: Control

• Age < 65 year;

• Co-morbidities

• Patients with life expectancy <3 months (terminally ill patients);

• Patients who have implanted defibrillators or pacemakers

• Damaged or very vulnerable skin around patch location

• Allergic to silicone or hydrocolloid adhesive materials

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-09-2016
Aantal proefpersonen:	30
Type:	Werkelijke startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5851
NTR-old	NTR6031
Ander register	: Philips Research

Resultaten