

Validation of an algorithm to assess functional mobility parameters based on inertial sensors

Gepubliceerd: 07-06-2021 Laatste bijgewerkt: 18-08-2022

We hypothesize that an IMU based motion-analysis system is a valid and feasible tool to assess functional mobility parameters.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON26816

Bron

Nationaal Trial Register

Verkorte titel

Smarten the Clinic 2.0 - Gait tool

Aandoening

Not relevant

Ondersteuning

Primaire sponsor: Sint Maartenskliniek

Overige ondersteuning: Smith&Nephew, ReumaNederland

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- Walking: stride length.

- Turning: peak turn velocity.
- Sit to stand transfers: rising time.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Walking, turning and sit-to-stand transfers are key elements in daily life functioning and are common affected in people with musculoskeletal disorders. Studies show that objective analysis of these basic can be used to assess someone's impairment in more detail. Inertial measurement units (IMUs) can facilitate fast and mobile assessment of walking, turning and rising from a chair in clinical practice. To date, several studies have been performed on gait and turning analysis with IMUs, showing accurate detection of spatiotemporal parameters and turning parameters in healthy participants. Moreover, studies have shown that a deviating gait cycle can be detected in patients with movement disabilities. Several companies offer packages consisting of IMUs and closed source software to assess functional mobility parameters. However, our own experience with the commercial software revealed that only ~10 percent of the total amount of steps were included for determining spatiotemporal gait parameters. Since commercial software is not specifically designed for analysis of deviating gait patterns, exclusion of even more steps occurs with deviating gait patterns. It is also not possible to link these commercial packages with other clinical data platforms, including the patient record system (HiX). Ensuring optimal integration with other IT systems will facilitate use of objective analysis of the basic activities in clinical practice. Therefore, algorithms have been developed within the Sint Maartenskliniek (SMK) to assess functional mobility parameters for the three basic activities. Objective: The main objective of this study is to validate the SMK algorithms against optical motion capture to determine functional mobility parameters.

Study design: Experiment validation study.

Study population: Healthy human volunteers, 40-90 years old, sample size: n=20.

Intervention: Participants will perform two overground walking tests, which includes walking up and down a 5 meter walkway for 2 minutes, and a triple L-test of 3x3 meters. Second, the participants will perform two treadmill walking tests, which includes (i) walking for 2 minutes at comfortable walking speed (normal strides) and (ii) walking for 2 minutes with shorter and longer strides at comfortable walking speed (walking asymmetrical). Participants will be equipped with 6 IMU sensors and 26 VICON reflective markers for gait analysis in all walking tests. During the treadmill walking tests, participants will also be equipped with a safety harness to prevent falling.

Main study parameters/endpoints: The accuracy of functional mobility parameters from the IMU-based analysis will be evaluated on the basis of agreement with the gold standard (i.e. marker-based optical motion capture system, VICON). To this end, Bland-Altman plots, correlation analyses and intra-class correlation coefficients (ICC) will be used to reflect the agreement between the assessed methods.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: The participant needs to visit the SMK once. Duration of preparation and tests

will be 60 to 90 minutes. Walking overground or at the treadmill with sensors and markers is not associated with any risks. Participants have no direct benefit from participating in the study. Participating in the study contributes to increasing knowledge about gait analysis and the validity of an IMU based system in order to analyze gait.

Doel van het onderzoek

We hypothesize that an IMU based motion-analysis system is a valid and feasible tool to assess functional mobility parameters.

Onderzoeksopzet

One single session

Contactpersonen

Publiek

Sint Maartenskliniek
Carmen Ensink

024-365 9140

Wetenschappelijk

Sint Maartenskliniek
Carmen Ensink

024-365 9140

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Healthy participants, aged 40-90 years old.

Belangrijkste redenen om niet deel te kunnen nemen

(Exclusiecriteria)

- Any diseases affecting gait or balance, such as osteoarthritis, neurological or neuromuscular disease or deformities of the lower extremities.
- BMI >30 kg/m².

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	21-04-2021
Aantal proefpersonen:	20
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies	
Datum:	07-06-2021
Soort:	Eerste indiening

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	NL9531
Ander register	CMO regio Arnhem-Nijmegen : 2021-8191

Resultaten