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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON26816

Source
Nationaal Trial Register

Brief title
Smarten the Clinic 2.0 - Gait tool

Health condition

Not relevant

Sponsors and support

Primary sponsor: Sint Maartenskliniek
Source(s) of monetary or material Support: Smith&Nephew, ReumaNederland

Intervention

Outcome measures

Primary outcome

- Walking: stride length.
- Turning: peak turn velocity.

- Sit to stand transfers: rising time.

Secondary outcome

- Walking: walking speed, stride time, stance time, swing time, step time, trunk range of motion.
- Turning: duration, number of steps within turn.
- Sit to stand transfers: lean angle.

Study description

Background summary

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.

Study objective

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

Study design

One single session

Contacts

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Eligibility criteria

Inclusion criteria

- Healthy participants, aged 40-90 years old.

Exclusion criteria

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

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	21-04-2021
Enrollment:	20
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	07-06-2021
Application type:	First submission

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
NTR-new	NL9531
Other	CMO regio Arnhem-Nijmegen : 2021-8191

Study results