Technology in Motion (TIM): Unobtrusive assessment of motor (dys)function

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Movement disorders (incl parkinsonism)
Study type	Observational non invasive

Summary

ID

NL-OMON43825

Source
ToetsingOnline

Brief title
TIM

Condition

- Movement disorders (incl parkinsonism)

Synonym
cerebrovascular accident (CVA, stroke); Parkinson's Disease (PD); tremor

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: NWO,Cinoptics, Leeuwarden,CleVR B.V., Delft,Motek Forcelink, Amsterdam

Intervention

Keyword: balance and gait, motor dysfunction, parkinson's disease, stroke

Outcome measures

Primary outcome

Kinematic parameters obtained for reaching and grasping (e.g., maximum active range of motion, accuracy, velocity and smoothness of reach and grasp movements), for gait and balance (e.g., step length, step time, gait asymmetry, performance on an obstacle avoidance task), and for tremor (frequency, amplitude) as a function of task- and environmental conditions.

Secondary outcome

Clinical test scores

For stroke patients in general:

Montreal Cognitive Assessment, Letter Cancellation Test, Beck Depression Index and Nottingham Extended Activities of Daily Living;

Additional for stroke patients participating in the *reaching and grasping* experiment:

Fugl-Meyer - Upper Extremity, Action Research Arm Test, Ashworth score of the elbow and wrist, Erasmus modification of the Nottingham Sensory Assessment - Upper Extremity and Michigan Hand Outcome Questionnaire;

Additional for stroke patients participating in the "gait and balance" experiment:

Timed Up-and-Go, 10 m walk test, Functional Reach test, Tinetti Balance Assessment, short version of the Berg Balance Scale, Falls Efficacy Scale *

International, Ashworth score of the knee and ankle, and the Modified Survey of Activities and Fear of Falling in the Elderly Scale

For PD patients in general:

Movement Disorder Society version of the Unified Parkinson Disease Rating Scale [MDS-UPDRS], the Scales for Outcomes in Parkinson*s Disease - Cognition [SCOPA-COG] and Psychiatric Complications [SCOPA-PC], Beck Depression Index and Questionnaire for Impulsive-Compulsive Disorders in Parkinson*s Disease * Rating Scale [QUIP-RS];

Additional for PD patients participating in the *reaching and grasping* experiment:

Michigan Hand Outcome Questionnaire;

Additional for PD patients participating in the "gait and balance" experiment:

Timed Up-and-Go, 10 m walk test, Functional Reach test, Tinetti Balance Assessment, short version of the Berg Balance Scale, Falls Efficacy Scale * International, the New Freezing of Gait questionnaire, the Modified Survey of Activities and Fear of Falling in the Elderly Scale, and the SEverity of Non-dopaminergic Symptoms in Parkinson*s Disease scale.

For patients with tremor:

Bain and Findley Clinical tremor rating scale, Bain and Findley tremor ADL scale

Other: age, sex, education level, work, dominant side, (most) affected side, disease duration, current medication use (type, dose and frequency),

retrospective and prospective falls (for the "gait and balance" experiment only), Hoehn and Yahr stage (for PD patients), Bamford classification (for stroke patients), visual acuity, outcome parameters related to usability (i.e., number of patients eligible for the study, number of patients invited, number of patients willing to participate, number of completed measurements, reasons for drop-out) and outcome parameters related to patient friendliness (i.e., duration of the experiment, participant experiences, numeric rating scale for pain and perceived strain).

Study description

Background summary

The prevalence of disorders that affect motor function, including neurovascular diseases (e.g., stroke), neurodegenerative diseases (e.g., Parkinson*s disease [PD]) and musculoskeletal pain conditions (e.g., osteoarthritis), is high and will further increase as a result of an ageing society, since the incidence of these disorders increases with age. Along with the foreseeable future shortage of healthcare supply, this raises the need for effective means to diagnose, monitor and treat disorders associated with motor dysfunction. A uniform evaluation of motor function that is efficient, patient-friendly, cost-effective, and that can be carried out on a large scale is currently not available. Emerging ICT technologies offer the required breakthrough opportunities (i.e., unobtrusive motion tracking and flexible task- and environmental manipulations) to address the shortcomings of traditional evaluations of motor dysfunction.

Study objective

The overall objective of this study is to develop patient friendly and unobtrusive techniques to characterize motor function. In this context we will use video cameras combined with depth sensors (RGB-D sensors, such as Microsoft KinectTM) and modern computer-vision techniques to perform accurate markerless tracking of the motion of patients to construct a *motion phenogram* that captures all key properties of the patient*s motions. Moreover, we will develop virtual and augmented reality techniques for examination of motor function during systematic manipulation of task- and environmental conditions in order

to challenge the patient*s adaptive ability, which may provide a more sensitive indicator of problems experienced in daily life. The specific objectives are: 1) to evaluate the usability and sensitivity of the markerless motion tracking devices for 3D-kinematic measurements of a) reaching and grasping movements of the upper limb and b) gait and balance in PD patients, stroke patients and controls, and for 3D-kinematic measurements of tremor of the arm and/or hand, in comparison to reference motion capture systems; 2) to compare unobtrusive motion outcome measures of stroke patients, PD patients, and healthy controls to establish whether expected differences between groups (based on physiological models of the diseases) can be detected; 3) to examine the association between unobtrusive motion parameters and corresponding (sub)scores on clinical tests, and to overall severity of motor dysfunction and disability; 4) to identify the set of (motor, sensory and/or cognitive) parameters that can best account for variance in clinical phenotype within each patient group.

Study design

Observational, cross-sectional study in which motion parameters of upper limb function and motion parameters of gait and balance function are collected in two groups of patients (PD and stroke) and healthy controls. These patient groups are included as demonstrator cases.

Besides administration of standard clinical tests, the study will consist of two experiments: one to evaluate reaching and grasping and one to evaluate gait and balance. Subjects will participate in one or both experiments, depending on whether the in- and exclusion criteria for the specific experiments are met. For a subject participating in both experiments, the two experiments will either be separated by a 10-15 min break, or will be conducted on separate days if the total duration of the first experiment (including clinical tests) exceeds 2 hours. In both experiments, the protocol consists of measurements at rest, followed by a set of active measurements, starting with assessment of basic motor functions and ending with a challenging task to evaluate the functional integration of motor, sensory and cognitive functions in various contexts.

In the *reaching and grasping* experiment, unrestricted movements of the arm and hand are recorded with a markerless motion capture device (complemented with an accelerometer and/or electromyography for validation purposes). The participants will be seated in a chair 2 m in front of a 60* flatscreen LED TV in normal upright sitting posture with their feet supported. The LED screen will be used for presenting task instructions, setting targets in a visual environment, and/or providing real-time visual feedback on a subject*s performance. An optical see-through head-mounted device will be used to display static as well as dynamic three-dimensional content in the subject*s environment to evaluate reaching and grasping under changing task- and environmental conditions. To optimize the augmented reality techniques for the "reaching and grasping" experiment, user experiences and usability will be

evaluated in a small pilot study. In the *gait and balance* experiment, full-body motions are recorded with markerless motion capture sensors while participants walk on a 10-meter walkway or while balance tests are performed on a 3-meter treadmill that includes force plates, which also allows for recording of shifts in center of pressure. Gait-dependent projections on the walkway are used to test gait adaptability under changing task- and environmental conditions (e.g., targeted stepping and obstacle avoidance).

In addition, tremor parameters will be collected in patients with tremor of the arm and/or hand. This "visual tremor assessment" will be combined with a scheduled appointment for tremor analysis at the Clinical Neurophysiology outpatient clinic.

Study burden and risks

The TIM protocol will align with current clinical practice (i.e., will not interfere with clinical decision making). TIM will add extra measurements of motor function using a markerless tracking device for assessment of unrestricted arm movements, gait, and balance, combined with augmented reality to evaluate these components in various contexts. When possible, measurements are performed during regular visits to the outpatient clinic, such that no extra visits of the patients are required. Depending on the patient*s preference, clinical tests and experiments will either be performed during a single visit or in two or three separate visits within one week. Measurements are non-invasive and bear minimal risks. Active participation of the subjects is required, but tasks will mostly involve submaximal effort. Actual measurement time per experiment does not exceed 90 minutes (excluding the clinical tests) and additional rest periods will be offered if necessary. For the *gait and balance* experiment, subjects will be asked to register their falls during a 6-month follow-up period. Travel costs to the hospital will be compensated on the basis of public transport (2nd class) or travel distance (¤ 0.19 per km). Additionally, participants will receive a VVV-voucher to the value of ¤20 for their participation.

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

General: 18 years or older, male/female, have command of the Dutch language.
Additional for stroke: survivor of a cerebrovascular accident (stroke)
Additional for PD: Diagnosed with PD according to the UK PD Brain Bank criteria
Additional for patients with tremor: tremor of the hand and/or arm, having a scheduled visit for tremor assessment at the Clinical Neurophysiology outpatient clinic at LUMC.
Additional for healthy controls: normal function of both arms, normal gait and balance function, normal cognitive function (MoCA score > 26), normal or corrected to normal vision

Exclusion criteria

General:
* additional neurological diseases and/or orthopedic problems interfering with hand/arm function or balance/gait function
* unable to comply with the protocol, i.e. insufficient general fitness or cognitive/communicative inability to understand instructions and participate in the measurement
* inability to walk with help of one person (for the *gait and balance* experiment only);Additional for stroke:
* <12 weeks after stroke
* established Hereditary Cerebral Hemorrhage With Amyloidosis - Dutch type (HCHWA-D)
* absence of any voluntary control of the paretic arm (for the *reaching and grasping* experiment only)

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-02-2016
Enrollment:	250
Type:	Actual

Ethics review

Approved WMO Date:	17-11-2015
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	27-01-2016
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	26-02-2016
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL54281.058.15

Study results

Date completed: 01-05-2018

Actual enrolment: 190

Summary results
Trial ended prematurely