FACED-UP: Fast Analysis of CErvical Dystonia * Unobtrusive and Precise

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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-OMON42860

Source
ToetsingOnline

Brief title
FACED-UP

Condition

- Movement disorders (incl parkinsonism)

Synonym
Cervical Dystonia (Torticollis); Essential Tremor

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Stichting Wetenschapsfonds Dystonie

Intervention

Keyword: Cervical Dystonia, Movement Analysis

Outcome measures

Primary outcome

Parameters related to postures and movements of the head (e.g., resting posture, maximum active range of motion, frequency and amplitude of tremor).

Secondary outcome

Clinical test scores (i.e., the TWSTRS, with subscales motor severity, disability and pain) for CD and ET patients.

Other: age, sex, disease duration, current medication use (type, dose and frequency), outcome parameters related to usability of the technique to be developed (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

Cervical dystonia (CD) is a chronic neurological condition that is characterized by intermittent or continuous muscle contractions leading to abnormal, often repetitive, movements and/or postures. This is often associated with pain and substantial limitations in (both physical and social) daily life functioning. For diagnosis and treatment selection, CD is mainly evaluated using clinical scales and questionnaires, such as the Toronto Western Spasmodic Torticollis Rating Scale (TWSTRS). These evaluations are subjective and strongly depend on the expertise of the clinician. Sometimes CD is misdiagnosed

as essential tremor (ET), as a consequence of which patients may incorrectly be injected with botulinum toxin (BTX) or, vice versa, unnecessarily be exposed to ineffective medication. Hence, there is a need for objective and user-friendly techniques that accurately capture the characteristics of CD. Emerging technologies such as unobtrusive motion tracking and computer vision combined with pattern recognition techniques offer the required breakthrough opportunities to address the shortcomings of traditional evaluations of CD.

Study objective

The primary objective of this study is to develop an objective, patient-friendly assessment setup with which relevant characteristics of movement disorders of the head, such as CD, can be obtained from video- and depth-images (obtained using Microsoft KinectTM) without markers and/or sensors being attached to the patients. The specific objectives are: 1) to develop computer-vision techniques for accurate evaluation of postural deviations and movement disorders (trembling, shaking) of the head from video- and depth images obtained with KinectTM cameras, and to establish whether this markerless motion capture system is able to capture the characteristic features of CD, i.e., whether differences between CD patients and control subjects can be detected for the concerning parameters; 2) to establish the association between outcome parameters derived from the markerless motion tracking system and the corresponding (sub)scores on clinical tests (i.e., the TWSTRS score) for CD patients; 3) to establish whether the markerless motion capture system is sensitive enough for 3D-kinematic measurement of the head (compared to reference motion capture systems using accelerometers and position-orientation sensors); and 4) to explore whether machine learning and pattern recognition techniques can be used to distinguish CD patients from ET patients.

Study design

Observational, cross-sectional study in which parameters of postures and movements of the head are collected in two groups of patients (CD and ET) and healthy controls.

In the Technology in Motion Laboratory at the LUMC, a standard video assessment protocol will be conducted according to the TWSTRS guidelines.The protocol starts with a recording at rest, followed by several head movements to determine the maximum active range of motion and recording of a *sensory trick* (if present). The participant*s movements are recorded with a markerless motion capture device (i.e., Microsoft KinectTM sensor) complemented with two small accelerometers and two position-orientation sensors for validation purposes. Based on these video recordings, the TWSTRS severity scale will be completed by an experienced neurologist. Computer vision and pattern-recognition techniques will be applied to the high-resolution color- and depth data obtained from the Microsoft KinectTM to accurately capture

characteristic features of CD.

Study burden and risks

The FACED-UP protocol will align with current clinical practice (i.e., will not interfere with clinical decision making). FACED-UP will add a short questionnaire (expected duration 5-10 minutes) and a measurement (expected duration 20 minutes) using a markerless tracking device for assessment of postures and movements of the head. When possible, measurements are performed during regular visits to the outpatient clinic, such that no extra visits of the patients are required. Measurements are non-invasive and bear minimal risks. Active participation of the subjects is required, but tasks will mostly involve submaximal effort. 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

All participants: 18 years or older, male/female, have command of the Dutch language
Additional for Cervical Dystonia (CD): Diagnosed with CD, registered at the LUMC
Additional for Essential Tremor (ET): Diagnosed with ET, registered at the LUMC

Exclusion criteria

* lesions or diseases of the central nervous system
* additional neurological and/or orthopedic problems interfering function of the neck, arm or back
* <8 weeks after treatment with BTX injections
* unable to comply with the protocol, i.e. insufficient general fitness or cognitive/communicative inability to understand instructions and participate in the measurement

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):	26-09-2016
Enrollment:	45
Type:	Actual

Ethics review

Approved WMO Date:	08-08-2016
Application type:	First submission
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	NL57792.058.16

Study results

Date completed:	20-01-2017
Actual enrolment:	45