Objective measurement of mental workload and stress in stroke

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Central nervous system vascular disorders
Study type	Observational non invasive

Summary

ID

NL-OMON45513

Source
ToetsingOnline

Brief title
Mental workload and stress in stroke

Condition

- Central nervous system vascular disorders

Synonym
Cerebrovascular accident (CVA), Stroke

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Onderzoeksgelden Rijndam Revalidatie

Intervention

Keyword: Mental Workload, Stress, Stroke

Outcome measures

Primary outcome

- Stress

* Objective: Heart rate variability, Heart rate, Galvanic skin respons and temperature.

* Subjective-momentary: Stress level score on a VAS-scale

* Subjective-general: Score on the Perceived stress scale (PSS)

* Subjective-ambulatory: Stress level is checked 12 times a day during the 5-days ambulatory measurement. Measured with an app.

- Mental workload

* Objective: Heart rate variability

* Subjective-momentary: Score on the Rating Scale of Mental Effort (RSME)

* Subjective-ambulatory: Mental workload is checked 12 times a day during the 5-days ambulatory measurement. Measured with an app.

Secondary outcome

- Demographics and phenotype of patients, such as: date of birth, gender , level of education, marital status, profession, sports activities/hobbies, stroke type, date stroke, therapy history since stroke, medication, comorbidity (CIRS scale),

- Baseline functioning

* Functional Ambulation Categories (FAC) score

* Berg balance Scale (BSS) score

* 10 meter walk test score

* Perceived stress scale (PSS) score

* Attention tasks score on d2 test, Trail Making Test (TMT) and auditory stroop

* Hospital Anxiety and Depression Scale (HADS) score

- Performance

* Number of wrong answers (Pasat test, stroop test), amount of sway, number of obstacles not avoided, walking pace

- Physical behavior:

*Ambulatory, objective: : Physical behavior of patients will be measured by the Activ8 system. he Activ8 distinguishes different activities and postures, namely, lying, sitting, standing, walking, cycling and running. Additionally the total energy expenditure can be determined.

* Ambulatory, subjective: Subjects fill out an electronic diary about the type of activities and duration of the activities performed during the 5-day ambulatory measurement 12 times a day.

Study description

Background summary

Nowadays, progress in the stroke rehabilitation process is measured by performance. However, how demanding a performance or a task is in terms of

mental workload (the costs) and stress associated with the performance remains unclear. Measuring mental workload and stress objectively during the rehabilitation process might be a valuable instrument to monitor progress in the rehabilitation trajectory. So far, objective representations of mental workload and stress have not been studied in this population.

Study objective

The main aim of this proof-of-principle project is to explore whether 1) standardized conditions (physical tasks, cognitive tasks and a combination of both) differing in task difficulty are associated with distinct physiological responses representative for mental workload and/or stress, and 2) whether results of the standardized measurements can be extrapolated to measurements in daily life conditions.

Study design

Subjects will perform a protocol of standardized motor (standing, walking) and cognitive tasks and a combination of cognitive and motor tasks, differing in motor and/or cognitive task difficulty. During/after each task performance, mental workload and stress will be measured both objectively and with questionnaires. Prior to the standardized lab measurements the subjects will have an intake, where we do some physical and cognitive tests. Additionally to the standardized lab measurement there will also be done a 5-day ambulatory measurement.

Intake:
The following tests will be done during the intake
* Functional Ambulation Categories (FAC)
* Berg Balance Scale (BBS)
* 10 meter walk (10MW) test
* Hospital Anxiety and Depression Scale (HADS)
* Perceived Stress Scale (PSS)
* Determining FAC level
* Attention tests, d2 and Trial making Test (TMT)

Standardized Lab measurement:
Executing three sets of tasks, consisting of all three tasks (within a set, increasing difficulty level). All tasks take 3 minutes, 2 minutes rest in between the tasks and 15 minutes rest between the task sets.
* Seated tasks (1. sitting, 2. sitting + PASAT test, 3. sitting + PASAT test).
* Standing tasks (1. standing, 2. Standing with eyes closed, 3. standing with eyes closed + auditory stroop task)
* Walking tasks (1. walking, 2. walking + obstacle avoidance task, 3. walking + obstacle avoidance task + auditory stroop task)
Questionnaires after each task, RMSE and VAS scale for momentary stress

Ambulatory measurements:
Subjects wear the devices, IMEC chest patch, IMEC chill band and Activ8 for 5 consecutive days. Every day, twelve times a day stress, mental workload level and activity will be monitored via an app.

Study burden and risks

Our inclusion criteria and consent procedure warrant the capacity of the subjects. The study will not directly benefit the participating subjects and is non-therapeutic in nature. However, this study will add to the accuracy of detection mental workload and stress in patients with stroke and will give us more insight in how demanding tasks are during a rehabilitation program. Ultimately, the study results will give us the opportunity to optimize the design of rehabilitation program on a personal basis in order to achieve the best result. Since all measurements are non-invasive and all tasks are minimally physically demanding, the risk of participation is minimal. The maximum duration of the test session is 2,5 hours and frequent breaks are provided.
The risk of wearing the measurement equipment is similar to the risk when wearing a commercial fitness tracker e.g. fitbit. The main risk is the development of skin irritations due to the chest patch. The CE marked patch however is designed by Delta to be biocompatible for measurements up to 7 days. The participants will be explicitly told that when they experience any irritations they can contact the experimenter and take off the patch. The medical doctor involved in this study, is aware of this risk and is also available for consults. Further measurements with both sensors are done in a safe, non-invasive manner. However, to exclude any risk, people with implanted devices such as a pacemaker or pregnant women are excluded from the study. We strongly believe that the potential benefits from this research for future stroke patients outweigh the minimal patient burden.

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

* Ischemic or haemorrhagic stroke * 6 months post-onset
* Functional ambulation category (FAC) <= 3/4/5
* age * 18 years
* Sufficient comprehension of the Dutch language

Exclusion criteria

* any premorbid progressive or non-progressive brain disease
* use of beta blockers or any other medication that influences the heart rhythm
* Pregnant women
* Persons with pacemakers or any other implantable device
* Brainstem infarction
* Diabetes
* Phatic disorders
* Arrhythmias

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-04-2017
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	22-02-2017
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL59099.078.16