Monotoring capacity and performance of stroke patients using instrumented clothing

No registrations found.

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

Summary

ID

NL-OMON22497

Source
NTR

Brief title
-

Health condition

stroke, instrumented clothing, monitoring, home situation.
beroerte, geïnstrumenteerde kleding, monitoren, thuissituatie

Sponsors and support

Primary sponsor: Roessingh Research and Development, Enschede
Source(s) of monetary or material Support: European Commission under the 7th Framework Programma: FP7-ICT-2011-7-287351

Intervention

Outcome measures

Primary outcome

Evaluation of possible data loss (% of successful data collection), evaluation of the data

(temporal, kinematic, kinetic and EMG of reaching tasks, walking and balance) and subjective evaluation of the system.

Secondary outcome

Standard clinical tests assessing capacity of walking, balance, arm/hand function and activities of daily life. Furthermore a predefined task is peformed.

Study description

Background summary

With the aging of the population, the incidence of stroke is increasing, especially in western countries. Depending on the patient’s impairments as a result of the stroke, a patient-specific rehabilitation program is started. When the patient has an adequate capacity to live at home, the patient is discharged and sent home. Sometimes patients show deterioration after leaving the rehabilitation centre. In some cases this is so severe that re-admission to a rehabilitation centre is necessary. Many times, the cause of the deterioration is unknown, since the patient’s period at home is like a black-box for the physician. If the physician would be able to monitor the patient’s motor function at home, he could intervene in case of deterioration and prevent an expensive re-hospitalisation. For this purpose, we develop instrumented clothing containing sensors that can eventually result in daily-life monitoring. In this pilot study, balance, walking and reaching tasks of stroke patients will be assessed in the home situation. The results will be evaluated and related to regular clinical tests and a predefined task, performed in a controlled laboratory setting.

Study objective

1) It is possible to record data delivering insights in the actual performance of activities of daily life using the Interaction system in stroke patients in the home environment.
2) It is expected that standard clinical test scores do not necessarily correlate with performance scores measured in the home setting.

Study design

There will be 3 measurement sessions, all performed within one week: 1 in a controlled laboratory setting, 2 in the home setting. Alle sessions will take about 3 hours.

Intervention

N/A: observational study
open, non-randomized proof of concept pilot study including measurements in a controlled setting and measurements in the home setting while wearing instrumented clothing.

Contacts

Public
Roessingh Research & Development
J. Reenalda
Enschede
The Netherlands
053-4875777
Scientific
Roessingh Research & Development
J. Reenalda
Enschede
The Netherlands
053-4875777

Eligibility criteria

Inclusion criteria

- previous stroke in the personal history, at least 6 months ago
- not receiving in-patient therapy
- age: 18 or above
- able to walk, a walking aid (unilateral or bilateral) is permitted
- able to read and understand questionnaires and able to execute commands
- able and willing to participate in the study
- signed informed consent

Exclusion criteria

- other musculoskeletal problems influencing walking, balance and reaching.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel

Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-04-2014
Enrollment:	10
Type:	Anticipated

Ethics review

Positive opinion

Date:	26-03-2014
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	NL4341
NTR-old	NTR4481
CCMO	NL47854.044.14

Study results

Summary results
N/A