Gaze behaviour of stroke survivors during upper limb movements

Published: 15-12-2016
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The primary objective is to gain insight into gaze behaviour of stroke survivors during upper extremity movements.

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

Summary

ID

NL-OMON45658

Source
ToetsingOnline

Brief title
Gaze tracking during upper extremity movement in stroke

Condition

- Central nervous system vascular disorders

Synonym
CVA, stroke

Research involving
Human

Sponsors and support

Primary sponsor: Revalidatiecentrum Het Roessingh
Source(s) of monetary or material Support: Europese Unie

Intervention

Keyword: CVA, Gaze behavior, stroke, Upper extremity

Outcome measures

Primary outcome

Main study parameters are related to (timing of) gaze behaviour during several reaching and object manipulation tasks such as proportions of task duration with gaze focused on task-relevant objects (TRO gaze), on task-relevant body parts (TRB gaze), and on task-irrelevant objects (TIO gaze) (expressed in percentages of total task duration).

Secondary outcome

To explore whether, and how, visuomotor behaviour of stroke survivors differs from healthy controls

To explore whether, and how, visuomotor behaviour of stroke survivors differs between participants with left- and right hemisphere strokes

Study description

Background summary

Upper limb weakness or hemiparesis is one of the foremost causes of disability after stroke. Since upper limb function is essential to perform activities of daily life (ADL) independently, assistive technologies are designed to help people recover physical interaction with their environment. For such devices to be applicable in ADL, their control needs to be highly intuitive and user friendly. A promising way for such intuitive control is intention detection based on gaze. Next to upper limb weakness, sensory impairments and unilateral spatial neglect are also common in the stroke population, which are likely to affect gaze behaviour. However, gaze behaviour of stroke survivors during active execution of upper extremity movements in 3D situations (i.e., real-life tasks with actual objects) is currently unknown.

Study objective

The primary objective is to gain insight into gaze behaviour of stroke

survivors during upper extremity movements.

Study design

The current study is an observational study with one measurement session per participant

Study burden and risks

The risks for the subjects are limited to a minimum. All tasks performed during the study will consist of arm movements that normally occur in ADL, while being seated, and will be performed within the abilities of each individual. All measurements take place in a controlled environment at a lab of Roessingh Research and Development with a researcher present. The researcher carefully monitors the participants during the measurements. Recordings of gaze behaviour are performed using a lightweight, wearable system (like glasses) equipped with camera*s and head movement trackers, without obstructing the person*s (head) movements.

Contacts

Public
Revalidatiecentrum Het Roessingh

Roessinghbleekweg 33b
Enschede 7522 AH
NL
Scientific
Revalidatiecentrum Het Roessingh

Roessinghbleekweg 33b
Enschede 7522 AH
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

In order to be eligible to participate in this study, a stroke survivor must meet all of the following criteria:
* Patients should be clinically diagnosed with unilateral, either right or left sided, middle cerebral artery stroke (ischemic or hemorrhagic)
* Between 18-80 years of age
* Time since onset of disease is at least one week
* Sufficient cognitive status to understand two-step instructions
* Patients should be able to lift their affected arm on the table and to grasp a cylindrical object while seated in a chair
* Provide written informed consent ;In order to be eligible to participate in this study, a healthy control subject must meet all of the following criteria:
* Between 18-80 years of age
* Sufficient cognitive status to understand two-step instructions
* Provide written informed consent

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
* People with severe acute pain of the (affected) arm and hand
* People having insufficient knowledge of the Dutch language to understand the purpose or methods of the study
- People withth visual deficits, either opthalmic (e.g. wearing glasses or lenses stronger than -5 or + 3) or cerebral
* Severe contractures limiting passive range of motion in the UE
* Co-morbidities limiting functional use of the arm and hand

Study design

Design

Study type: Observational non invasive

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-04-2017
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	15-12-2016
Application type:	First submission
Review commission:	METC Twente (Enschede)
Approved WMO Date:	02-06-2017
Application type:	Amendment
Review commission:	METC Twente (Enschede)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 24214
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL59420.044.16
Other	Wordt nog bij NTR aangemeld
OMON	NL-OMON24214