Validation of the Actiwatch method for the measurement of upper extremity activity in the daily life of stroke patients.

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The aim of this study is to determine the concurrent and divergent validity of the Actiwatch method in patients with subacute and chronic stroke.

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

Summary

ID

NL-OMON32421

Source
ToetsingOnline

Brief title
Actiwatch pilot study

Condition

- Central nervous system vascular disorders
- Vascular haemorrhagic disorders

Synonym
cerebral haemorrhage/-infarction, CVA

Research involving
Human

Sponsors and support

Primary sponsor: Hoensbroek Revalidatiecentrum (HRC)

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: accelerometer, stroke, upper extremity use, validity

Outcome measures

Primary outcome

Actual amount of upper extremity use in daily life, measured by the Actiwatch

method (ratio score) and the Dutch Motor Activity Log

Secondary outcome

The arm function sub scale and the mobility sub scale of the Stroke Impact

Scale

Study description

Background summary

During the last years, stroke has become the leading cause of long-term disability world-wide. Impaired function of the upper extremity (hemi paresis) is one of most frequent symptoms after stroke. Also on the long term a great percentage of this patient population is confronted with arm and hand function impairments, resulting in limitations in daily functioning. Additionally, dissatisfaction about the own abilities to participate in society can occur in stroke patients.
Because of the impact of upper extremity impairments, training of arm use plays an important role in stroke rehabilitation. To determine the effects of various rehabilitation techniques, a lot of scientific research is done in this field.
One parameter in this kind of research is de actual use of the affected upper extremity in tasks of daily life. It is shown that this actual amount of use can differ significantly from the functional ability measured in performance tests.
With the Actiwatch method, a relatively new accelerometer-based measurement has been introduced. It is designed to measure movement of limbs over a long period of time. By putting an Actiwatch on both wrists upper extremity movement can be registered.

Study objective

The aim of this study is to determine the concurrent and divergent validity of the Actiwatch method in patients with subacute and chronic stroke.

Study design

In this validation study, the concurrent validity will be measured by comparing the Actiwatch method with the MAL-26 and the arm function sub scale of the SIS. Divergent validity will be determined by comparison of the Actiwatch method with the mobility sub scale of the SIS, measuring a different construct than the amount of upper extremity use.

Study burden and risks

Patients will be asked to visit the rehabiliation centre to participate in an interview and a questionnaire (in total approximately 1 to 1,5 hour). Next to that, patients have to wear 2 watch-like devices around their wrists for 3 days. This last intervention has little to no consequences for performing daily activities. Per participant the least laborious/time-consuming way will be chosen to start the measurement (putting on the Actiwatch devices).
There is no risk for the health of the participants.

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

1) a history of single stroke, at least 6 weeks previously, resulting in a paresis of the arm/hand;
2) no severe cognitive problems;
3) no severe aphasia;
4) experience of spending days in the home situation after stroke;
5) knowledge of the Dutch language;
6) minimum of 18 years of age

Exclusion criteria

The presence of uncontrolled medical conditions or conditions other than stroke that might impair upper extremity function.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	26-03-2008
Enrollment:	45
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC SRL Stichting Revalidatie Limburg (Hoensbroek)

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	NL22449.022.08