Wii-habilitation of Upper Extremity Function in Children with Cerebral Palsy, an explorative study

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Ethical review Approved WMO

Status Recruitment stopped

Health condition type Congenital and peripartum neurological conditions

Study type Interventional

Summary

ID

NL-OMON34747

Source

ToetsingOnline

Brief title

WiiCP

Condition

Congenital and peripartum neurological conditions

Synonym

CP; Congenital static encephalopathy

Research involving

Human

Sponsors and support

Primary sponsor: Revalidatiecentrum Het Roessingh

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

Intervention

Keyword: Cerebral Palsy, Rehabilitation, Upper Extremity Function, Wii-habilitation

Outcome measures

Primary outcome

The main study parameter is the Melbourne assessment of unilateral upper limb function.

Secondary outcome

Secondary outcome measurement is the ABILHAND-kids. A User Satisfaction Questionnaire and a Health professional usability questionnaire are used to assess the usability of the Wii-computer.

Study description

Background summary

Cerebral Palsy (CP) is the most common cause of physical disabilities in children in Western countries. Impaired upper extremity function is the main problem for half of the children diagnosed with CP. Although it is recognized that it is important to integrate play and leisure in therapy in order to achieve benefits, children often find conventional therapy boring and repetitive. Recent technologies such as Robotica, Virtual reality and gaming seem to meet these requirements. These technologies may also provide safety, adaptability, task specificity, real time performances feedback and independent training for rehabilitation.

Study objective

The primary objective of this explorative study is to evaluate the training effect on the upper extremity function of the (most) affected arm in unilateral activity, in children with unilateral and bilateral spastic Cerebral Palsy using the WiiTM computer, which is a Virtual Reality intervention. The secondary objective is to evaluate the training effect on execution of bilateral activity in daily life as perceived by the caregivers. Another secondary objective is to evaluate the user satisfaction and usability of WiiTM

computer training for the user and the health professional.

Study design

This explorative intervention study consists of one pre- and one post training measurements of functional aspects of upper extremity movements.

Intervention

The children will attend 30 minute training sessions of VR exercise games training on the Wii-computer 2 times a week for 6 Weeks.

Study burden and risks

It is expected that this study will benefit children with CP in de future. We also anticipate a positive outcome on upper extremity function on the participating children. Because current therapies for improving upper extremity function will be stopped during the study the extra burden for the children is limited to the measurements and inclusion procedure (2 hours in total). 6 Hours will be spent on the actual exercises. There are no risks involved in participating in the inclusion procedure and measurements. The vast majority of injuries reported in literature due to playing on a Wii-computer are accidental or due to overuse. They are preventable by the controlled environment, supervision of a physiotherapist and the limited time spend on a Wii-computer. There is no extra risk in participating in this study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adolescents (12-15 years) Adolescents (16-17 years) Children (2-11 years)

Inclusion criteria

- -Ages between 6 and 15 years
- -Have impairment of the upper extremity primarily or secondary to unilateral of bilateral spastic Cerebral Palsy
- -Melbourne Assessment precentage score 11% or higher
- -Have the ability to hold on to the game controller
- -Improvement of upper extremity function is a current goal for rehabilitation
- -Have normal or corrected to normal vision and hearing

Exclusion criteria

- -Epilepsy not under control with medication.
- -Impairment of the upper extremity due to other causes than primarily or secondary to cerebral palsy
- -Unable to understand instructions for using the intervention

Study design

Design

Study type: Interventional

Masking: Open (masking not used)

Control: Uncontrolled

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Primary purpose: Treatment

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 19-10-2010

Enrollment: 10

Type: Actual

Ethics review

Approved WMO

Date: 04-06-2010

Application type: First submission

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

No registrations found.

In other registers

Register ID

CCMO NL30777.044.10