Virtual Reality gaming to improve upper limb functionality in children with Cerebral Palsy

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The goal of this study is to examine the feasibility of a home-based VR intervention to improve upper limb functionality in patients with CP. Primary research question: 1. Is VR-based gaming a feasible method to provide a rehabilitation intervention...

Ethical review	Approved WMO
Status	Completed
Health condition type	Movement disorders (incl parkinsonism)
Study type	Observational non invasive

Summary

ID

NL-OMON51967

Source
ToetsingOnline

Brief title
Home-based VR Rehabilitation for Children with CP.

Condition

- Movement disorders (incl parkinsonism)

Synonym
Cerebral Palsy

Research involving
Human

Sponsors and support

Primary sponsor: Sint Maartenskliniek
Source(s) of monetary or material Support: Interreg NWE

Intervention

Keyword: CP, Rehabilitation, VR

Outcome measures

Primary outcome

1. Logbook.

2. System usability scale.

Secondary outcome

1. Melbourne assessment 2

2. Upper limb reaching test.

3. Range of motion.

Other:

* Inter-rater reliability (ULRT).

* Test-retest reliability (ULRT).

* Construct validity (ULRT).

Study description

Background summary

Cerebral Palsy (CP) is known as a neurological disorder that involves multiple permanent movement and posture constraints. Approximately 1 in 500 neonates are born with CP, resulting in a worldwide population of 17 million people (1). Nearly 50% of CP cases happens to express either unilateral or bilateral impaired hand- and arm function, both having major impact on quality of life (2).
Children with CP often have a diminished awareness of remaining upper limb capacity (3). Besides, they develop a learned non-use, which represents suppressed movement of the affected limb (4-5). Beating learned non-use is a major target in upper limb rehabilitation interventions, however difficult to

achieve. Each time individuals perform activities of daily living (ADLs) with their affected upper limb, they experience negative feedback and possibly even failure in performing certain actions. This may ultimately lead to a progressive suppression (5). Therefore, it is a great challenge to encourage the use of affected upper limbs in daily life.
One of the most promising ways to reduce learned non-use is constraint-induced movement therapy (CIMT). During CIMT, the non-affected (or less affected) upper limb is constrained, resulting in a forced use of the affected limb. Subsequently, individuals have to perform ADLs with their affected limb, thereby improving their skills.
One relatively new technology that is becoming more regularly applied in rehabilitation practice is Virtual Reality (VR). In a way, VR-based gaming shows some similarities to CIMT. VR games are controlled either uni- or bimanually. When unimanually-controlled games are performed with the affected upper limb, movements of the unaffected hand are completely ineffective. This mimics the principle of forced use. To some degree, also bimanually-controlled games result in a forced use of the affected upper limb.
Additionally, VR could help in the engagement in rehabilitation programs, as virtual environments and gaming increases enjoyment and motivation (7, 8) and therefore therapy adherence (9). Accordingly, VR-based gaming may have the potential to improve upper limb functionality in children with CP. Therefore, this study aims to investigate the feasibility of a home-based VR intervention to improve upper limb functionality in children with CP.

Study objective

The goal of this study is to examine the feasibility of a home-based VR intervention to improve upper limb functionality in patients with CP.

Primary research question:
1. Is VR-based gaming a feasible method to provide a rehabilitation intervention for children with CP?
* Do participants achieve a satisfying amount of rehabilitation practice, indicating good therapy compliance?
* Is the Oculus Quest VR headset usable for rehabilitation?

Secondary research question:
2. Does VR-based rehabilitation using commercially-available games result in an improved upper limb functionality in children with CP.

Other objectives:
3. Determine interrater reliability, test-retest reliability and construct validity of the Upper Limb Reaching Test (ULRT) in children with CP.

Study design

Study type: Feasibility study.
Study duration: Approximately 9 months.
Setting: Sint Maartenskliniek & home-setting of participants.

Study burden and risks

The risks in this study are neglectable. Furthermore, participants may improve their occupational- and/or functional ability of their hand and arm.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)

Inclusion criteria

Patient population:
* Inclusion criteria:
* CP children with a unilateral or severely asymmetric, bilateral spastic movement impairment.
* Age 10-20 years old.
* Manual Ability Classification System (MACS) scores I, II or III.
* House classification of 1, 2 or 3.

Healthy subjects:
* Inclusion criteria:
* Age 10-20 years old.

Exclusion criteria

Patient population:

Exclusion criteria:
* Significant persisting motion sickness in VR.

Healthy population
* Exclusion criteria:
* Any kind of condition, disease or disorder that affects upper limb functionality (i.e. muscular disorder, fracture, bruises, etcetera).

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	12-04-2021
Enrollment:	24
Type:	Actual

Medical products/devices used

Generic name:	VR glasses
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	18-03-2021
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	26-04-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL76462.091.21