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Toyra® project: virtual reality in the rehabilitation of upper limbs in people with tetraplegia

Submission date
26/05/2015

Recruitment status
No longer recruiting

Registration date
29/05/2015

Overall study status
Completed

Last Edited
18/11/2021

Condition category
Injury, Occupational Diseases, Poisoning

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Paralysis is the loss of the ability to move one or more muscles, often as a result of damage to the brain, nerves or spinal cord. Two of the most common causes of paralysis are stroke and spinal cord injury. Sometimes paralysis can be temporary, but paralysis caused by serious injury such as a broken neck is most often permanent. Tetraplegia is a type of paralysis where both the arms and the legs are affected; loss of feeling and movement in the limbs may be partial or total, depending on the severity of injury. Physiotherapy is often used to help people with tetraplegia to maintain fitness and potentially improve function in the upper limbs. The aim of physiotherapy is to help people regain independence in activities of daily living, such as functional mobility (being able to get about in general), bathing, self-feeding and toilet hygiene. A new therapy being tested in the rehabilitation of people affected by paralysis is virtual reality (VR). VR is a computer-constructed environment based on real (or imagined) life, in which the user (e.g. the patient) can experience sensations (e.g. touch and sight). VR environments can be experienced using a specially designed headset or viewed on a computer screen. There is some evidence to suggest that VR systems may help improve rehabilitation outcomes when used alongside standard treatments such as physiotherapy. The aim of this study is to see whether a rehabilitation programme which includes the Toyra® VR system works better to improve function in the paralysed upper limbs of people with tetraplegia compared to standard treatment alone.

Who can participate?
Adults with motor complete spinal cord injury at the level of C5 to C8 less than 12 months from time of injury.

What does the study involve?
Participants are randomly allocated into one of two groups. Those in group 1 (intervention group) are given 15 half hour sessions with the Toyra® system 3 days a week for 5 weeks alongside standard treatment. Those in group 2 (control group) are given standard treatment alone. Standard treatment for all participants includes routine occupational and physical therapy for 90 minutes a day, 5 days a week. Participants are asked to complete various questionnaires

and take part in physical assessments at the start of the trial, at the end of the trial, and again 3 months later.

What are the possible benefits and risks of participating?
VR has been shown to have many advantages when used alongside traditional rehabilitation therapy. Furthermore, users have reported VR to be enjoyable and motivating. It can also increase the intensity of the exercises through repetition, which also enables the induction of neuroplasticity. Risks associated with participation in the trial include motion sickness or vertigo induced by the use of the VR system.

Where is the study run from?
National Spinal Cord Injury Hospital - SESCAM (Spain)

When is the study starting and how long is it expected to run for?
September 2010 to January 2015

Who is funding the study?
National Spinal Cord Injury Hospital - SESCAM (Spain)

Who is the main contact?
Ms I Dimbwadyo Terrer

Contact information

Type(s)
Scientific

Contact name
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Contact details
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Additional identifiers

EudraCT/CTIS number
2015-002157-35

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
C.E.I.C. 48/06-2012

Study information

Scientific Title
Toyra® project: virtual reality for assessing and rehabilitation of upper limbs in people with tetraplegia

Study objectives
1. Treatment with the Toyra® system produces improvement in motor limitations of the upper limbs (ULs), and favours autonomy in people with activities of daily living (ADL) which involve the ULs.
2. The effect of treatment with Toyra® system on UL motor limitations appear after 15 sessions with the ADL module.
3. Objective assessment results obtained with the virtual reality (VR) system after treatment with Toyra® match the obtained with the clinical and functional scales.
4. Better functional results are achieved by applying the Toyra® system as a complement to traditional therapies.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Hospital Complex of Toledo, Spain, 11/06/2012, ref: C.E.I.C. 48/06-2012.

Study design
Randomised clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
https://www.dropbox.com/s/kqcn0vrstive7um/Informed%20consent_english.pdf?dl=0

Health condition(s) or problem(s) studied
Spinal cord injury

Interventions
All participants receive conventional therapy, consisting of routine occupational therapy and physiotherapy (e.g. active and passive mobilisations, strengthening exercises of the upper limb (UL) and activities of daily living (ADL) training). Conventional therapy is provided for an hour and a half/day, 5 days/week.
1. Experimental group (EG) have 15 sessions with the Toyra® system for 5 weeks, 30 minutes /day, 3 days/week in addition to conventional therapy. The virtual reality (VR) intervention is carried out by an experienced occupational therapist. The VR treatment consists of one activity of daily living-based virtual reality game to induce UL motor skills. The main objective of the

game is to achieve the maximum degree of autonomy that is possible in basic ADL. The monitor displays several daily objects (spoon, fork, comb or sponge), and asks the participant to reproduce the movements necessary to perform the corresponding activities (eating, combing hair or washing the face). The user is able to choose the preferred avatar, which represents his /her movements in a mirror viewed in real time. The session offers three different difficulty levels, based on changes in the objects' size, height and speed of appearance. Subjects perform the task with their dominant arm (the arm used to perform the basic daily living tasks in the real word).
2. Control group (CG) are given conventional therapy.

Intervention Type
Mixed

Primary outcome measure
Change in upper limb function. All participants are evaluated twice: at the beginning of the study and at the end, using a set of clinical and functional scales. The evaluation is performed the day before starting the VR treatment (pre-assessment) and the day after finishing (post-assessment). A sample from each group will be followed up and assessed 3 months after the study (follow up-assessment), to measure the stability of the changes. In this period both groups continue with conventional therapy. The functional examination uses four scales:
1. The Functional Independence Measure (FIM) consisting of 18 items organised in six categories, four corresponding to motor functions (self-care items, sphincter control, mobility items, and locomotion) and two corresponding to cognitive functions (communication, psychosocial, and cognitive). The lowest and highest scores of the total ranged from 18 to 126.
2. The Spinal Cord Injury Independence Measure (SCIM III) has 16 items divided into three functional areas: self-care, respiration and sphincter management, and mobility. Total score can vary from 0 (minimal) to 100 (maximal). Only the self-care sub-score has been considered in this study, because it has been previously shown that the self-care category of the SCIM III and several of its items correlate well with UL strength and capacity tests in persons with tetraplegia.
3. The Barthel Index (BI) consists of 10 items: eating, bathing, grooming, dressing, bowels, bladder, toilet use, transfers (bed to chair and back), mobility (on level surfaces) and stairs. Total score is from 0 to 100.
4. Motricity Index (MI) which assesses power and range of active movement rated for shoulder abduction, elbow flexion, and pinch between the thumb and index finger. Each movement is rated on a 0-100 point scale.

Secondary outcome measures
Satisfaction with the virtual reality rehabilitation system. The level of satisfaction is assessed after VR training in the experimental group using the Quebec User Evaluation of Satisfaction with Assistive Technology 2.0 (QUEST), an instrument specifically designed to measure satisfaction with a broad range of assistive technology devices in a structured and standardised way. The test includes 12 items, related to device characteristics (n=8) and assistive technology services (n=4). The scoring method rates from 1 (not satisfied at all) to 5 (very satisfied). Only the items related to device characteristics are used for this study, due to the lack of external assistive services. Therefore, the maximum possible score is 5 for each item, and 35 for the total scale. We also use a satisfaction survey (Likert scale) to identify the satisfaction not only with the VR systems features, but also with the rehabilitation and functional aspects related to VR systems. The Likert scale consists of 20 items rated from 0 (not satisfied at all) to 5 (very satisfied), including questions about systems features, VR activities and motivation. The maximum possible score is 5 for each item, and 100 for the total scale.

Overall study start date
01/09/2010

Completion date
01/01/2015

Eligibility

Key inclusion criteria
1. Aged 18 and over
2. Less than 12 months from the injury
3. Motor complete spinal cord injury according to the American Spinal Injury Association (ASIA) impairment scale at the level of C5 to C8 (A-B ASIA level)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
31

Total final enrolment
31

Key exclusion criteria
1. History of traumatic or cognitive pathology that can affect UL movements
2. Technology addiction
3. Epilepsy
4. Pregnancy
5. Normal or corrected-to normal vision and hearing

Date of first enrolment
01/01/2011

Date of final enrolment
31/08/2014

Locations

Countries of recruitment
Spain

Study participating centre
National Spinal Cord Injury Hospital - SESCAM
Finca la peraleda S/N
Toledo
Spain
45071

Sponsor information

Organisation
National Spinal Cord Injury Hospital - SESCAM

Sponsor details
Biomechanics and Technical Aids Department
Finca la peraleda S/N
Toledo
Spain
45071

Sponsor type
Hospital/treatment centre

Website
http://www.neuralrepairhnp.es/index.php/biomecanica-y-ayudas-tecnicas

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
National Spinal Cord Injury Hospital - SESCAM (Spain)

Results and Publications

Publication and dissemination plan
We have sent two papers related to this study in April and May of 2015, and we are preparing a third article to send at the end of June 2015. The main objective of the first paper is to analyse the correlations between functional scales and kinematic data collected during the execution of upper limb functional tasks in a virtual reality environment. In the second paper we investigate

the effects of conventional therapy combined with an intensive and repetitive virtual reality program on upper limb function in people with sub-acute complete tetraplegia compared with only conventional therapy, and to study the satisfaction of patients with the virtual reality system. The third article will analyse the effects of conventional therapy combined with an intensive and repetitive virtual reality program on upper limb kinematic parameters in people with sub-acute complete tetraplegia compared with only conventional therapy.

Intention to publish date
01/12/2015

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/01/2018	18/11/2021	Yes	No