ISRCTN27760662 https://doi.org/10.1186/ISRCTN27760662

Effectiveness of virtual reality devices in the rehabilitation of adults with stroke

Submission date
15/06/2020

Recruitment status
No longer recruiting

Registration date
16/06/2020

Overall study status
Completed

Last Edited
05/04/2023

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
A stroke is a serious life-threatening medical condition that happens when the blood supply to part of the brain is cut off. According to the World Health Organization, cerebrovascular accidents (stroke) are the second leading cause of death and the third leading cause of disability. One of the most frequent problems after stroke is upper limb (UL) impairments such as muscle weakness, contractures, changes in muscle tone, and other problems related to coordination of arms, hands or fingers. These impairments induce disabilities in common movements such as reaching, picking up or holding objects and difficult activities of daily living (ADLs) such as washing, eating or dressing, their participation in society, and their professional activities. Most of people experiencing this upper limb impairment will still have problems chronically several years after the stroke. Impairment in the upper limbs is one of the most prevalent consequences of stroke. For this reason making rehabilitation is an essential step towards clinical recovery, patient empowerment and improvement of their quality of life.
The greatest functional recovery is achieved in the first weeks and months after the damage. However, patients can improve in tasks, producing a neuronal reorganization even long after the stroke. Despite the latter, survivors continue to experience long-term disability and a decline in their health-related quality of life.
The aim of the project is to increase and deepen the existing knowledge about brain recovery after a stroke and evaluate the effectiveness of virtual reality systems for rehabilitation and improvement of quality of life of the adults stroke.

Who can participate?
Adults diagnosed with stroke (18-85 years old).

What does the study involve?
Rehabilitation programs using virtual reality. The use of games specifically designed for the rehabilitation process.
Virtual reality devices: HandTutor, 3DTutor and Rehametrics.
Participants were randomly assigned to the experimental group (EG) or control group (CG).
EG participants received 15 individual training sessions with virtual reality systems (50 min., five a week), provided by an occupational therapist. Each session is divided into three parts: 5 min. of HandTutor glove placement; 20 min. of HandTutor training; 5 min. of Rehametrics placement

(bobath ball, chair, weights, etc.) and 20 min. of Rehametrics training.
The selected exercises are repeated every day. Every day the difficulty increases (number of objects, speed, etc.).
The control group was not treated with virtual reality. They were only doing motor training in physical and occupational therapy.

What are the possible benefits and risks of participating?
The possible benefits of using virtual reality technology in rehabilitation processes with stroke adults include improvement of upper limb mobility, the balance and walking and improvement in the performance of daily life activities.
The possible adverse effects include fatigue, muscle pain and headaches.

Where is the study run from?
The study has been designed from the University of Castilla La Mancha (Spain) and rehabilitation sessions with technology based on virtual reality are being developed in the University General Hospital of Talavera de la Reina.

When is the study starting and how long is it expected to run for?
January 2018 to April 2021

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
1. Marta Rodríguez-Hernández
Marta.RHernandez@uclm.es
2. Dra. Begoña Polonio-López
Begona.Polonio@uclm.es

Contact information

Type(s)
Scientific

Contact name
Prof Marta Rodríguez-Hernández

ORCID ID
https://orcid.org/0000-0003-2182-8870

Contact details
University of Castile-La Mancha
Faculty of Science Health
Avenida Real Fábrica de Sedas, s/n
Talavera de la Reina
Spain
45600
+34 627832682
Marta.RHernandez@uclm.es

Type(s)

Scientific

Contact name
Dr Begoña Polonio-López

ORCID ID
http://orcid.org/0000-0003-2922-7519

Contact details
Faculty of Health Sciences
University of Castilla-La Mancha
Av. Real Fábrica de Sedas s/n
Talavera de la Reina
Spain
45600
+34 (0)682247830
Begona.Polonio@uclm.es

Additional identifiers

EudraCT/CTIS number
No

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
TECHNOREHAB: randomized clinical trial for the technological rehabilitation of adults with stroke

Acronym
TECHNOREHAB

Study objectives
1. The use of virtual reality devices improves the upper limb mobility in patients post-ictus
2. The use of virtual reality devices improves the balance and walking in patients post-ictus
3. The use of virtual reality exercises increases functional independence in patients post-ictus
4. Participation in a virtual reality exercise program produces changes sensation of well-being and quality of life

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 17/04/2018, Clinical Research Ethical Committee of the Talavera de la Reina Integrated Management Area (CEIC del AGI de Talavera de la Reina, Hospital Nuestra Señora del Prado. Ctra. Nacional V, km. 114, 45600, Talavera de la Reina (Toledo), Spain; +34 (0)925 80 36 00 Ext. 86.316; varroyo@sescam.org), ref: 12/2018

Study design
Longitudinal prospective randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Motor injuries and functional dependence in adults with stroke

Interventions
Rehabilitation programs using virtual reality. The use of games specifically designed for the rehabilitation process.
Virtual reality devices: HandTutor, 3DTutor and Rehametrics.
The assignment to each of the groups was parallel. Participants were randomly assigned to the experimental group (EG) or control group (CG), with an allocation ratio of 1:1.
Randomisation process: sealed envelope.
Blinding of trial participants and therapist was not possible.

Experimental group: participants received 15 individual training sessions with virtual reality systems (50 min., five a week), provided by an occupational therapy and training of motricity and fuerza with physical and occupational therapist of the hospital. Each session is divided into three parts: 5 min. of HandTutor glove placement; 20 min. of HandTutor training; 5 min. of Rehametrics placement (bobath ball, chair, weights, etc.) and 20 min. of Rehametrics training. The selected exercises are repeated every day. Every day the difficulty increases (number of objects, speed, etc.).

Control group: the control group was not treated with virtual reality. They were only doing motor training in physical and occupational therapy.

Intervention Type
Behavioural

Primary outcome measure
1. The impact of stroke on daily life is measured using SIS 3.0 scale at baseline, the end of study (15 sessions), 3 and 6 months
2. Walking capacity and balance is measured using Tinetti Test at baseline, the end of study (15 sessions), 3 and 6 months
3. The motor function of the upper limb is measured using Ara-T and Fugl-Meyer at baseline, the end of study (15 sessions), 3 and 6 months
4. Perceived quality of life is measured using EuroQool-5L Test at baseline, the end of study (15 sessions), 3 and 6 months

Secondary outcome measures
1. Resistance to movement in the paretic upper limb is measured by the Modified Ashworth Scale at baseline, the end of study (15 sessions), 3 and 6 months
2. User satisfaction with the device is measured with the Quebec Scale at the end of study (15 sessions)

Overall study start date
30/01/2018

Completion date
12/03/2020

Eligibility

Key inclusion criteria
1. Age between 18 and 85 years old
2. Diagnosed stroke
3. Difficulties motor skills of the upper limb
4. Dependence in daily life activities
5. Time of evolution since diagnosis: maximum 6 months
6. No other disabling pathology prior to the injury
7. Not having a life expectancy of less than 6 months
8. Acceptance and signature of the informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
23 participants were assigned to the experimental group (EG) and 23 to the control group (CG). 43 participants completed the intervention period and follow-up evaluation. The control group lost three participants due to the start of the COVID-19 pandemic in Spain.

Total final enrolment
46

Key exclusion criteria
1. Presence of other neurological disorders
2. Severe heminegligency
3. Psychiatric disorders that hinder participation
4. Signature of revocation of consent

Date of first enrolment
17/04/2018

Date of final enrolment
12/03/2020

Locations

Countries of recruitment
Spain

Study participating centre
University of Castilla La Mancha
Faculty of Science Health
Avenida Real Fábrica de Sedas s/n
Talavera De La Reina
Spain
45600

Study participating centre
University General Hospital
Carretera de Madrid
Avenida de Extremadura, KM 114.
Talavera de la Reina
Spain
45600

Sponsor information

Organisation
University of Castile-La Mancha

Sponsor details

Faculty of Science Health
Avenida Real Fábrica de Sedas, s/n
Talavera de la Reina
Spain
45600
+34 925268800 Ext. 5623
Begona.Polonio@uclm.es

Sponsor type
University/education

Website
https://www.uclm.es/toledo/facsalud

ROR
https://ror.org/05r78ng12

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
30/01/2021

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Marta Rodríguez-Hernández (Marta.RHernandez@uclm.es).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	three-month follow-up results	10/03/2021	16/03/2021	Yes	No
Results article	results	28/04/2021	26/01/2022	Yes	No

Results article	04/04/2023	05/04/2023	Yes	No