

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

<b>Submission date</b> 15/06/2020	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 16/06/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 05/04/2023	<b>Condition category</b> Circulatory System	<input type="checkbox"/> 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

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## Contact information

### Type(s)

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### Contact name

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## Additional identifiers

**Clinical Trials Information System (CTIS)**

No

**ClinicalTrials.gov (NCT)**

Nil known

**Protocol serial number**

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

## **Study type(s)**

Treatment

## **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(s)**

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

**Key secondary outcome(s)**

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)

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Total final enrolment**

46

**Key exclusion criteria**

1. Presence of other neurological disorders
2. Severe hemineglect
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

## ROR

<https://ror.org/05r78ng12>

# Funder(s)

## Funder type

Other

## Funder Name

Investigator initiated and funded

# Results and Publications

## 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?
<a href="#">Results article</a>	three-month follow-up results	10/03/2021	16/03/2021	Yes	No
<a href="#">Results article</a>	results	28/04/2021	26/01/2022	Yes	No
<a href="#">Results article</a>		04/04/2023	05/04/2023	Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes