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Gymnasium for Robotic Rehabilitation (Gimnasio de Rehabilitación Robótica)

Submission date 13/07/2015	**Recruitment status** No longer recruiting	✓ Retrospectively registered ? Protocol not yet added ? SAP not yet added ✓ Results added ? Raw data not yet added ✓ Study completed
Registration date 10/08/2015	**Overall study status** Completed	
Last Edited 19/09/2016	**Condition category** Circulatory System	

Plain English Summary
Background and study aims
Stroke is a condition that affects about 15 million people every year. It is caused by an interruption of the blood supply to the brain caused by rupture of a blood vessel or its obstruction. Today, stroke is one of the main causes of disability in the developing and the developed world. It is believed that intensive long-term therapy can diminish the level of disability, but for many people, especially in developing countries, treatment is not affordable. The aim of this study is to find if a gymnasium for robotic rehabilitation can provide a cost and labor effective alternative therapy for stroke patients.

Who can participate?
Patients between 21 and 75 years old, diagnosed with hemiplegia (paralysis of one side of the body) from a stroke that occurred no less than 6 months before the study.

What does the study involve?
Participants will be randomly assigned to one of two groups. One of the groups will receive 24 sessions of traditional therapy, which consists of physical and occupational therapy according with the recommendations of the physician. The other group will receive the same 24 sessions of therapy in the robotic gym, consisting of several workstations based on game therapies and occupational therapy. Each station is configured specifically for the needs of each person and changes depending the person's progress.

What are the possible benefits and risks of participating?
Possible benefits for the participant include improvement in arm and/or leg function, but this is not guaranteed. Risks associated with the participation in this study include frustration, fatigue, discomfort, soreness, swelling and skin irritation.

Where is the study run from?
Centro de Rehabilitación y Educación Especial (CREE) (Mexico).

When is the study starting and how long is it expected to run for?
From November 2010 to February 2014.

Who is funding the study?
Consejo Nacional de Ciencia y Tecnología (Mexico).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Protocol/serial number
N/A

Study information

Scientific Title
Gymnasium for Robotic Rehabilitation (Gimnasio de Rehabilitación Robótica): a randomized controlled trial

Acronym
Robot Gym

Study hypothesis
The hypothesis of the protocol is that the "Gymnasium for Robotic Rehabilitation" (Robot Gym) is capable to provide a low-cost and labor efficient alternative to post stroke rehabilitation. All this while being more or as efficient as traditional therapies in the State of Chihuahua, Mexico.

Ethics approval required

Old ethics approval format

Ethics approval(s)
1. Marquette University Institutional Review Board, 04/03/2011
2. Comité del Centro de Rehabilitación y Educación Especial Turno Vespertino (Committee of the Center for Rehabilitation and Special Education Afternoon Shift), 23/09/2011

Study design
Single-centre interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Quality of life

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

Condition
Stroke

Interventions
Patients were randomly allocated to receive either traditional or Robot Gym rehabilitation therapy.

The robot Gym therapy consist of six stations of computer and motor-assisted devices which aid in the cognitive enhancement and motor rehabilitation of upper and lower extremities. The first station is formed by a low cost system for arm rehabilitation called Theradrive; this device allows patients to realize therapy while playing commercial videogames with a Logitech wheel. Second and third stations house the Bioness devices (NESS H200 and L300), which provides functional electrical stimulation to hand and foot, respectively. The MOTOMed devices are on the fourth and fifth stations to help motor rehabilitation on the upper and lower limbs through a series of games played by doing movements similar to bicycling. The last station is formed by the Capitains Log Brain-Trainer, which is a commercial cognitive rehabilitation therapy system to improve neuroplasticity.

The traditional therapy is formed by the standard physical therapy, which includes physical and occupational therapy, personalized for each patient. This type of therapy seeks to improve the range of motion and muscle strength, as well as improve the performance of activities of daily living.

Intervention Type
Device

Primary outcome measure
All selected patients will receive the following tests to measure our primary outcomes one week before the start of the 24 therapy sessions and one week after the end of the 24 sessions:
1. Kinetic and kinematic of lower and upper extremity data using the motion analysis lab
2. Motivational survey
3. Fugl Meyer for upper and lower extremities
4. Functional Test
5. Box and blocks
6. Timed Get up and Go
7. Six Minutes Walk
8. Ten Meters Walk

Secondary outcome measures
1. Minimental Test at the initial consult with the physiatrist, approximately 2 weeks before the 24 sessions of therapy and during the final consult 2 weeks after the end of the intervention.
3. Geriatric Depression Scale at the initial consult with the physiatrist, approximately 2 weeks before the 24 sessions of therapy and during the final consult 2 weeks after the end of the intervention.
3. Pain and exercise survey (using visual analogue scale) are performed every third session starting from session one through the end of the sessions
4. Motor Activity Log applied one week before the beginning of therapy and one week after the end of the 24th session
5. Visual Neglect Test (Albert's test) at the initial consult with the physiatrist, approximately 2 weeks before the 24 sessions of therapy and during the final consult 2 weeks after the end of the intervention.

Overall study start date
01/11/2010

Overall study end date
12/02/2014

Eligibility

Participant inclusion criteria
1. Patients who were clinically diagnosed with hemiplegia from stroke occurred no less than 6 months prior to the study
2. Medically stable
3. Between 21 and 75 years old
4. The subject must have the left side affected
5. The subject must have the ability to sit for 60 minutes and to stand assisted or unassisted for 30-40 minutes
6. They must not be more than mildly depressed and moderately cognitively disabled
7. Must have residual motion in shoulder and elbow, and residual movement in leg flexion, extension and hip adduction (Brunnstrom scale ranging from 2 to 5, Ashworth scale over 4 and Manual Muscular Test >1 and <3)

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
24 subjects was the target population for the grant but permission to IRB was to recruit 25% more of that number to allow for patient drop out. The purpose is to have at least 6 subjects in each group to allow for statistical comparisons

Participant exclusion criteria
1. Psychiatric disorders
2. Excessive spasticity in upper or lower extremities that prevent engaging in therapy activities
3. Excessive joint pain
4. Pregnant or breastfeeding
5. More than a score of four in Ashworth test
6. Unwillingness to participate in the protocol

Recruitment start date
01/01/2012

Recruitment end date
30/09/2013

Locations

Countries of recruitment
Mexico

Study participating centre
Centro de Rehabilitación y Educación Especial (CREE)
5th street and Samaniego street W/N
Santa Rosa
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Mexico
31060

Sponsor information

Organisation
Marquette University (USA)

Sponsor details

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Sponsor type
University/education

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ROR
https://ror.org/04gr4te78

Funder(s)

Funder type
Government

Funder Name
Consejo Nacional de Ciencia y Tecnología

Alternative Name(s)
National Council of Science and Technology, Mexico, CONACYT

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Mexico

Results and Publications

Publication and dissemination plan
Results will be published and disseminated in international conferences and scientific journals.

Intention to publish date
01/05/2011

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	15/09/2016		Yes	No