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Effect of virtual reality on physical and mental health in patient with stroke

Submission date
20/10/2014

Recruitment status
No longer recruiting

Registration date
29/10/2014

Overall study status
Completed

Last Edited
29/10/2014

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
This study is aimed at comparing the effects of virtual reality (VR) based rehabilitation, group-based rehabilitation, and no rehabilitation at all on upper extremity (arms, upper body) function, daily activities, and general quality of life. Through this study, we would be able to suggest better ways of improving physical and mental health in people who have suffered a stroke and are living in the community.

Who can participate?
People who have suffered a stroke and are at least 30 years old.

What does the study involve?
Participants are randomly allocated into one of three groups. Those in group 1 take part in a newly developed VR-based rehabilitation programme. Those in group 2 take part in a conventional group-based rehabilitation programme. Those in group 3 are in a control group and dont receive any rehabilitation at all. Participants in both rehabilitation programmes attend 30 minute training sessions three times a week for eight weeks.

What are the possible benefits and risks of participating?
The results of this study will be used to assess the success of VR-based and group-based rehabilitation which, in turn, will help in developing successful rehabilitation treatments for stroke patients in the community.

Where is the study run from?
The Applied NeuroDynamics Laboratory of Korea University (South Korea).

When is study starting and how long is it expected to run for?
August 2014 to December 2014.

Who is funding the study?
The Korea National Rehabilitation Institute (South Korea)

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

Secondary identifying numbers
N/A

Study information

Scientific Title
Effect of virtual reality on physical and mental health in patient with stroke: a randomized controlled trial

Study objectives
This study is aimed at comparing the effects on upper extremity function, activities of daily living performance, and quality life between virtual reality-based rehabilitation, group-based rehabilitation, and non-rehabilitation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Institutional Review Board of Korea University. Seoul, Korea, 19/06/2014, ref: KU-IRB-14-76-A-2

Study design

Randomized three arm controlled trial.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, Please use contact details below to request a patient information sheet.

Health condition(s) or problem(s) studied
Stroke

Interventions
Newly developed motion free Virtual Reality (VR)-based rehabilitation and group-based rehabilitation will be conducted in a sitting position. Both rehabilitations will include 30-minute training program three times a week for eight weeks. Each of five-minute will be offered for a warm up and cool-down training. The therapeutic method, which were included in both rehabilitation is a proprioceptive neuromuscular facilitation (PNF) technique for the patient with unilateral stroke. Both interventions will be supervised by certified physical therapists for emergency.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Upper extremity function:
1. Fugl-Meyer Assessment (FMA), measured pre- and post-intervention
2. Manual Function Test (MFT), measured pre- and post-intervention
3. Box & Block Test (BBT), measured pre- and post-intervention
Activities of daily living performance:
1. Modified Bathel Index (MBI), measured pre- and post-intervention
Health-realted quality of life:
1. Short Form Health Survey (SF-12), measured pre- and post-intervention

Secondary outcome measures
1. Satisfaction (5 point Likert scale), measured post intervention
2. Intention to adherence (5 point Likert scale), measured post intervention

3. Expectation for therapeutic effect (5 point Likert scale), measured post intervention
4. Attendance rate, measured during intervention
5. Enjoyment, difficulty(0~10), measured post intervention

Overall study start date
01/08/2014

Completion date
31/12/2014

Eligibility

Key inclusion criteria
1. Community-dwelling patient with stroke aged over 30 years
2. Onset of a unilateral stroke at least one month previously

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
40

Key exclusion criteria
1. Severe cognitive impairments unable to follow instructions
2. Listening or visual impairments
3. Dementia, headaches, or dizziness
4. Other neurologic, neuromuscular, or orthopedic disease

Date of first enrolment
01/08/2014

Date of final enrolment
31/12/2014

Locations

Countries of recruitment
Korea, South

Study participating centre
161 Jeongneung-ro, Seongbuk-gu
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Sponsor information

Organisation
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Sponsor type
University/education

ROR
https://ror.org/047dqcg40

Funder(s)

Funder type
Government

Funder Name
The Korean National Rehabilitation Institute (South Korea)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration