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Limitations of motor brain activity – use of virtual reality for simulation of therapeutic interventions

Submission date
29/07/2019

Recruitment status
No longer recruiting

Registration date
01/08/2019

Overall study status
Completed

Last Edited
15/09/2020

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
Persons with acquired brain injury (ABI) and traumatic brain injury (TBI) are in need of neuro-rehabilitation/repair. Virtual anatomical interactivity (VAI) can take a digital game-like form, where the survivors can perform exercises and tasks in virtual world. The aims of the study were to determine for stroke and traumatic brain injury survivors:
1) the effects, if any, of virtual limb control on improving movements of impaired limbs; and
2) brain changes, if any, related to motor improvements.

Who can participate?
Stroke and traumatic brain injury survivors aged over 21 years, who are actively engaged in physical and occupational therapy

What does the study involve?
Traditional stroke therapy (hands-on by therapists, with or without assistive devices) was tested independently of any other therapy, secondly by adding virtual limb control to traditional therapy and, thirdly by survivors using only a standard computer mouse to point a cursor to all or any part of an anatomically realistic virtual limb with true range of motion. Survivors controlled virtual limbs to simulate a desired unimpaired physical movement. Three therapeutic modalities illustrated the difference between traditional therapy, a physical solution to a neurological problem (brain neural insult) and virtual limb control therapy, a neurological solution to a neurological problem.

What are the possible benefits and risks of participating?
The benefits are supplementary, non-invasive, self-administered rehabilitation exercises in an entertaining video game-like format which encourages repetition. Feedback, while virtual visuo-motor is adopted as real by survivor-participants as next best to real feedback and since survivors were hemiparetic, next best to assisted limb movement therapy. The risks were non-existent. PAGEs are presented in a slow video game format.

Where is the study run from?
Kladruby Rehabilitation Facility, Czechia

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

Who is funding the study?
3DPreMotorSkills, LLC, USA

Who is the main contact?
Vincent Macri,
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Study website
http://www.neurojungle.com

Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
001-1

Study information

Scientific Title

Pre-Action Games and Exercises: Utility of virtual reality as supplemental stroke survivor rehabilitation in stroke and/or traumatic brain injury survivors to examine change in functional motor performance and volumetric cortical grey matter

Acronym
PAGEs

Study objectives
Stroke survivors controlling virtual limbs will improve functional use of impaired limbs and experience cortical grey matter change

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 03/02/2015, Ethics Board of Rehabilitation Centre Kladruby (Rehabilitační ústav Kladruby
Kladruby 30, 257 62 Kladruby u Vlašimi; (+420) 317 881 219 ;kristyna.hoidekrova@rehabilitace.cz), ref: No reference number.

Study design
Interventional randomised 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 to request a participant information sheet.

Health condition(s) or problem(s) studied
Ischemic stroke and traumatic brain injury

Interventions
The intervention included traditional physical and occupational therapy and controlling virtual limbs to simulate unimpaired physical movement.

The subjects were divided into three groups:
- Group A received traditional stroke rehabilitation (VAI) therapy only

- Group B received VAI and physical/occupational therapy (P/OT)
- Group C received P/OT only.
(Group A participants were out-patients, groups B and C included in-patients)

Motor skills were evaluated by muscle strength (hand key pinch strength, grasp and three-jaw pinch) and active range of motion (AROM) of shoulder, elbow, and wrist. Their changes were analysed by ANOVA, ANCOVA and one-tailed Pearson correlation analysis. MRI data for brain changes were analysed using voxel-based morphometry and correlated with quantified motor skills.

The total duration of treatment was 10 weeks 3 sessions per week approximately 30 minutes per session. Funding limitations precluded follow-up. Randomisation was based on 100% volunteer sign-ups for the study.

Intervention Type
Other

Primary outcome measure
Measured at baseline (1-3 days before intervention) and post-intervention (10-weeks).
1. Changes in cortical grey matter volume measured using MRI data analyzed using voxel-based morphometry and correlated with quantified motor skills
2. Motor skills evaluated by muscle strength (hand key pinch strength, grasp and three-jaw pinch) and active range of motion (AROM) of shoulder, elbow, and wrist

Secondary outcome measures
None

Overall study start date
10/12/2014

Completion date
30/04/2015

Eligibility

Key inclusion criteria
1. Stroke survivors
2. Traumatic brain injury survivors
3. Actively engaged in physical and occupational therapy
4. Age range: 21 years and older
5. Gender: male or female

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
35

Total final enrolment
35

Key exclusion criteria
1. Patients unable to comprehend use of standard computer mouse to point to and control virtual limbs

Date of first enrolment
10/01/2015

Date of final enrolment
31/01/2015

Locations

Countries of recruitment
Czech Republic

Study participating centre
Kladruby Rehabilitation Facility
Kladruby
Czech Republic
349 61

Sponsor information

Organisation
3DPreMotorSkills, LLC

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Sponsor type
Research organisation

Website
http://www.neurojungle.com

Funder(s)

Funder type
Industry

Funder Name
3DPreMotorSkills, LLC

Results and Publications

Publication and dissemination plan
It is currently under peer review with a first set of reviewers comments by the Journal of NeuroEngineering and Rehabilitation

Intention to publish date
01/09/2019

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	12/09/2020	15/09/2020	Yes	No