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AMERICAN CONGRESS OF REHABILITATION MEDICINE

Archives of Physical Medicine and Rehabilitation

journal homepage: www.archives-pmr.org

Archives of Physical Medicine and Rehabilitation 2018;99:834-42

ORIGINAL RESEARCH

Virtual Reality for Upper Limb Rehabilitation in Subacute and Chronic Stroke: A Randomized Controlled Trial

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Abstract

Objective: To evaluate the effectiveness of reinforced feedback in virtual environment (RFVE) treatment combined with conventional rehabilitation (CR) in comparison with CR alone, and to study whether changes are related to stroke etiology (ie, ischemic, hemorrhagic).

Design: Randomized controlled trial.

Setting: Hospital facility for intensive rehabilitation.

Participants: Patients (N=136) within 1 year from onset of a single stroke (ischemic: n=78, hemorrhagic: n=58).

Interventions: The experimental treatment was based on the combination of RFVE with CR, whereas control treatment was based on the same amount of CR. Both treatments lasted 2 hours daily, 5d/wk, for 4 weeks.

Main Outcome Measures: Fugl-Meyer upper extremity scale (F-M UE) (primary outcome), FIM, National Institutes of Health Stroke Scale (NIHSS), and Edmonton Symptom Assessment Scale (ESAS) (secondary outcomes). Kinematic parameters of requested movements included duration (time), mean linear velocity (speed), and number of submovements (peak) (secondary outcomes).

Results: Patients were randomized in 2 groups (RFVE with CR: n=68, CR: n=68) and stratified by stroke etiology (ischemic or hemorrhagic). Both groups improved after treatment, but the experimental group had better results than the control group (Mann-Whitney U test) for F-M UE ($P<.001$), FIM ($P<.001$), NIHSS ($P\leq.014$), ESAS ($P\leq.022$), time ($P<.001$), speed ($P<.001$), and peak ($P<.001$). Stroke etiology did not have significant effects on patient outcomes.

Conclusions: The RFVE therapy combined with CR treatment promotes better outcomes for upper limb than the same amount of CR, regardless of stroke etiology.

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Stroke is the third cause of death and the first cause of disability worldwide,[1] regardless of ethnicity and citizenship, dramatically affecting the independence and quality of life of survivors. Impairment of motor function is commonly present after stroke because of the involvement of the brain areas responsible for planning and execution of movements (eg, primary motor cortex, anterior frontal lobe).[2,3] Recent studies have also shown that other functions, mainly represented in the posterior parietal cortex, are involved in decision-making for the production of voluntary movements (eg, spatial attention, spatial awareness, multisensory integration of feedback).[4] Another important factor which interferes with performance of motor tasks after stroke is the severity of associated cognitive impairments.[5] Regardless of stroke etiology (ie, ischemic, hemorrhagic), clinical sequelae are devastating. Therefore, rehabilitation is provided to patients regardless of onset. Nevertheless, evidence has shown that patients gain greater functional improvement after intracerebral hemorrhage (10%−15% of all strokes), than after ischemic infarct.[6] This

Clinical Trial Registration No.: NCT01955291.
Disclosures: none.

0003-9993/18/$36 - see front matter © 2018 by the American Congress of Rehabilitation Medicine
https://doi.org/10.1016/j.apmr.2018.01.023

finding was also observed in patients with hemorrhagic stroke treated in a virtual environment in the preliminary study of this clinical trial.[7]

The main objective of motor rehabilitation after stroke is to promote movement learning[8] with the aim to reduce the effect of disease on loss of function and to improve quality of life. Recent advances to improve the efficacy of rehabilitation modalities suggest to include the principles of motor learning in feasible clinical treatments.[9] Therefore, recent findings have demonstrated that repetitive, intensive, and random practice of functional tasks may be required to modify neural structures involved in motor control and learning processes.[1,10] A significant boost to promote neuroplasticity during rehabilitation care came from the use of innovative computer-based technologies (eg, virtual reality, robotics).[11-14] These technology-based modalities enrich the traditional rehabilitation setting by increasing specific feedback on results and motor performance. Many studies have shown that augmented feedback is able to modulate sensorimotor cortical activity, by facilitating learning in selected brain networks.[15]

Virtual reality acts as an augmented environment where feedback can be delivered in the form of enhanced information about knowledge of results and knowledge of performance.[7] Regarding clinical applications for rehabilitation, the translation of functional skills during the recovery process can be promoted by adapting the complexity of requested motor tasks to the functional level of each single patient.[9] Several studies demonstrated that treatment enriched by reinforced feedback in virtual environment (RFVE) may be more effective than conventional rehabilitation (CR) to improve motor function of the upper limb after stroke.[7,11,16] RFVE may contain elements useful to maximizing movement learning (eg, providing repeated and varied task practice, augmenting feedback on achieved results). RFVE has been tested in clinical trials providing insights into specific stroke rehabilitation and benefits that can be obtained by using enriched virtual environment.[17-19] Although several studies have been conducted on this topic, there is still a lack of large clinical and randomized trials that involve and assess different stroke etiologies in relation to augmented virtual feedback. Therefore, to overstep this literature limitation, we compared effects on patients with ischemic stroke with effects on patients with hemorrhagic stroke. There is also deficiency in the literature on the potential of combining virtual therapy with other treatments and its influence on poststroke recovery. Therefore, this aspect has also been analyzed in this study.

In this trial, we hypothesized that performing a movement in enhanced virtual environment could have significant effect on upper limb motor function and that stroke etiology could be a factor influencing the recovery process.

The aims of this study were to explore whether the RFVE intervention, combined with CR, could improve motor function more than the same amount of CR applied alone, after both ischemic and hemorrhagic stroke, and to observe whether the type of stroke (ie, ischemic, hemorrhagic) may influence recovery gains.

List of abbreviations:

CR	**conventional rehabilitation**
ESAS	**Edmonton Symptom Assessment scale**
F-M UE	**Fugl-Meyer upper extremity scale**
NIHSS	**National Institutes of Health Stroke Scale**
RFVE	**reinforced feedback in virtual environment**
VRRS	**Virtual Reality Rehabilitation System**

Methods

Participants and design

A single-blind, randomized controlled trial was completed among inpatients affected by a first episode of stroke because of both ischemic and hemorrhagic etiologies (fig 1). Subjects who had a stroke onset up to 12 months before enrollment were included in the study. The following criteria were considered for exclusion: cognitive impairment (defined as score <24 on the Mini-Mental State Examination),[20] having previously received RFVE treatment, presence of apraxia (defined as a score <62 points on the De Renzi test),[21] impairment of verbal comprehension (defined as a score >40 errors on the Token test),[22] evidence in clinical history of neglect, upper extremity complete hemiplegia (score of 4 points on the upper limb subitem of the National Institutes of Health Stroke Scale [NIHSS]),[23] presence of upper limb sensory disorders (defined as <1 point on items shoulder, elbow, wrist, and thumb in the sensitivity section of the Fugl-Meyer scale), fracture, and joint dislocation.

The internal review board of the hospital approved the study, and all patients were informed about the aim and experimental procedures before enrollment; therefore, written informed consent was obtained from all of them. Individuals included in the study were randomly assigned to experimental or control group according to a simple randomization technique (computerized random numbers). The randomization sequence was generated at the start of the trial using a computerized program (Microsoft Excel[a]). The allocation sequence was concealed from the principal investigator enrolling patients in sequentially numbered, opaque, sealed envelopes. The researcher responsible for randomization was independent from the assessors, assuring blindness to treatment allocation and randomization procedures, respectively. Because of the treatment modality, it was not possible to blind patients regarding treatment received. In the experimental group, patients received treatment based on RFVE, whereas in the control group CR was provided. Moreover, both groups received an additional hour per day of CR. In this regard, the amount of therapy, defined as hours of treatment provided, was comparable between groups (ie, 2h/d, 5d/wk for 4wk: 40h overall), but the therapeutic modalities (ie, RFVE and CR, twice CR) representing the independent variable determining the effects in the trial were not. Both therapeutic modalities were provided by physiotherapists employed in the institute and trained for RFVE and CR application. Moreover, each single treatment was executed by different clinicians blind to study aims. The CR treatment consisted of whole-body exercises which were selected autonomously by the clinician. The additional hour consisted of RFVE or CR. The exercises in the RFVE group were selected from the library of the Virtual Reality Rehabilitation System (VRRS) program[b] or created ad hoc, whereas exercises in the CR group were replicated from the virtual scenarios. However, both treatments were personalized and coherent to the patient's condition. Therefore, not all the tasks and movements were matched in the 2 treatments (ie, CR, RFVE). All patients enrolled in this study were inpatients of the rehabilitation institute and were treated during their stay in the hospital. According to Italian health policies, it is regular practice to admit patients >1 year after stroke to rehabilitation hospitals, if they still present with rehabilitation needs.