

Improvement of motor imagination and manual hability through virtual reality, selective and non-selective functional electrical stimulation: study protocol for a randomized controlled trial

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Improvement of motor imagination and manual hability through virtual reality, selective and non-selective functional electrical stimulation: study protocol for a randomized controlled trial

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Abstract

Motor imagery is a cognitive process that has been shown to be useful in the rehabilitation process after brain injury. Moreover, functional electrical stimulation (FES) has also been shown to be an effective intervention in many parameters, and there is some evidence of its contribution to the improvement of motor imagery capacity.

To compare the improvements in motor imagery parameters, strength and manual dexterity obtained using virtual reality, FES and selective FES based on multi-field electrodes in healthy people.

Type of study: randomized, controlled clinical trial, with four branches, with blinded third-party assessment. 80 healthy university students will be assigned to the intervention groups. All, except those who participate in the control group, will undergo 5 consecutive sessions of 30 minutes each in non-dominant arm, of the corresponding intervention. Initial, post-intervention and a third follow-up assessment will be conducted. Movement imagery Questionnaire revised (MIQ-RS) and chronometry (timing) will be administered for the assessment of motor imagery, strength will be measured using a digital dynamometer, Nine Hole Peg Test and Box and Blocks test will be administered for manual dexterity assessment.

As results, an improvement in motor imagery is expected, especially in the groups receiving FES. Improvements are also expected in the intervention groups in the rest of the parameters assessed in the non-dominant arm.

Ethic and dissemination: The study has been approved by the Ethic Committee of Burgos University (IO 2/2023). It will be conducted according to Helsinki declaration, and the requirements established in Spanish legislation. The results will be disseminated through open-access and peer-review journal, and conference presentations.

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OF MOTOR IMAGINATION AND MANUAL HABILITY THROUGH VIRTUAL REALITY, SELECTIVE AND NON-SELECTIVE FUNCTIONAL ELECTRICAL STIMULATION: STUDY PROTOCOL FOR A RANDOMIZED CONTROLLED TRIAL

Abstract

Background: Motor imagery is a cognitive process that has been shown to be useful in the rehabilitation process after brain injury. Moreover, functional electrical stimulation (FES) has also been shown to be an effective intervention in many parameters, and there is some evidence of its contribution to the improvement of motor imagery capacity.

Objective: To compare the improvements in motor imagery parameters, strength and manual dexterity obtained using virtual reality, FES and selective FES based on multi-field electrodes in healthy people.

Methods: Type of study: randomized, controlled clinical trial, with four branches, with blinded third-party assessment. 80 healthy university students will be assigned to the intervention groups. All, except those who participate in the control group, will undergo 5 consecutive sessions of 30 minutes each in non-dominant arm, of the corresponding intervention. Initial, post-intervention and a third follow-up assessment will be conducted. Movement imagery Questionnaire revised (MIQ-RS) and chronometry (timing) will be administered for the assessment of motor imagery, strength will be measured using a digital dynamometer, Nine Hole Peg Test and Box and Blocks test will be administered for manual dexterity assessment.

Results: As results, an improvement in motor imagery is expected, especially in the groups receiving FES. Improvements are also expected in the intervention groups in the rest of the parameters assessed in the non-dominant arm.

Ethic and dissemination: The study has been approved by the Ethic Committee of Burgos University (IO 2/2023). It will be conducted according to Helsinki declaration, and the requirements established in Spanish legislation. The results will be disseminated through open-access and peer-review journal, and conference presentations.

Trial Registration: Registered in clinicaltrials.com, ID: NCT06109025

Keywords: Electric Stimulation Therapy, Motor Imaginery, Virtual Reality Exposure Therapy, Hand Strength, Hand Injuries.

Introduction

Motor imagery (MI) is defined as the cognitive process of imagining the movement of one's own body part without actually moving that body part [1]. The procedure of testing via electroencephalography the MI, mainly consists of five phases: signal data acquisition, data pre-processing, feature extraction, feature classification and device control interface [2]. The data acquisition phase includes MI signal collection, signal digitization and data storage. The data pre-processing phase involves data filtering, data cleaning, data transformation, etc. The feature extraction phase extracts discriminative features containing useful information from electroencephalogram signal data. The feature classification phase uses the extracted features as input to train machine learning models. Finally, in the device control interface phase, the categorized signals are translated into commands to control devices, such as robots, home appliances, wheelchairs [3].

MI can help disabled and elderly people to perform a specific task through imagination without physically performing any limb movement [1]. Taking this into account, different techniques have been proposed in recent years that could be useful in improving MI in people with neurological pathology. Among the most used techniques are: mirror therapy, virtual reality or augmented reality [4]. Although it has been studied less, it has also been shown that the use of electrical stimulation could help improve MI parameters in this type of pathologies [5].

Neuromuscular stimulation is an application of electrical stimulation used in movement rehabilitation [6]. Functional electrical stimulation (FES) is a subtype of neuromuscular stimulation in which the stimulation assists functional and purposeful movements [7]. Electrical currents are applied to motor nerves producing muscle contractions in a sequence that allows them to perform different tasks. Examples might include grasping a key, holding a toothbrush, standing up, cycling or walking [8].

FES was developed in the 1960s, emphasizing its potential as an assistive technology [9]. Since then, FES has evolved into an important therapeutic intervention that clinicians can use to help people with neurological diseases to regain motor abilities [10].

FES device technology has traditionally relied on conventional electrodes. However, multi-field surface electrodes have emerged, consisting of groups of several small conducting fields, which can be activated/deactivated and configured independently [11].

The Fesia Grasp (Fesia Technology, Donostia-San Sebastian, Spain) [12] is the only commercial FES hand rehabilitation device based on multi-field electrodes (32 cathodes and 8 anodes). It delivers trains of biphasic pulses to different electrode fields in an asynchronous manner to generate contractions of the forearm muscles (it can trigger at least eight different flexion and extension movements of the wrist and fingers) in order to restore motor function in persons with neurological injuries [11].

Hand rehabilitation is sometimes a lengthy process, and motivation is crucial to the patient's outcome. Moreover, the outcome of the treatment depends not only on the rehabilitation process of the practitioner, but also on the patient's motivation for the training [13]. One of the ways to make rehabilitation more attractive is to incorporate game-based protocols, such as 2D games, 3D games, virtual reality (VR) games [14], augmented reality games [15], etc.

Notably, the use of VR in game-based training protocols meets both the physiological and psychological needs of patients [13]. VR creates a dynamic and motivating environment by merging touch, hearing and vision, which makes patients more engaged in clinical or home training [14]. This technology could also be useful when improving MI.

The objective of this study is to compare the improvements in MI parameters, strength and manual dexterity obtained using VR, traditional FES and selective FES based on multi-field electrodes in people without neurological pathology.

Methods

Design and study population

This is a parallel-group, randomized, controlled clinical trial. Single-centre, with blinded third-party assessment. As for the sample, four parallel groups (N=80) made up of university students are planned. A first group will receive an intervention based on multi-field FES with the Fesia Grasp device (selective FES multi-field); another group will receive only FES with the Globus Elite electrostimulation device (traditional FES based on conventional electrodes); a third group will receive an intervention based on VR; and finally, a control group, which will not receive any treatment. The sample will be randomised through a computer application for assignment to one of the groups included in the study.

Inclusion criteria are: a) To be of legal age and sign the informed consent form; b) Not to suffer any

pathology in the upper limb such as tendinitis, oedema, fractures, etc. c) Intact skin (without breaks, scratches, cuts, and other types of superficial or deep lesions) on the non-dominant arm where the devices will be placed if applicable. Exclusion criteria are considered to be: a) Severe medical problems. b) Use of pacemakers. c) Pregnancy. d) Peripheral neuropathies. e) Presence of other neuromuscular pathologies.

Participants may leave the study in the following cases: At their own request, without giving reasons; Adverse events occur that prevent them from continuing the study; Failure to complete the treatment; Failure to complete the sessions within the schedule established for each one. The reason for withdrawal will be recorded in the database.

Procedure

There are three phases of the project: Preparation, Data Collection, and a final phase of Analysis and Reporting.

Preparation phase: This phase includes drafting the project, obtaining ethics committee approval (IO 2/2023), registering it on the Clinicaltrials.gov platform (NCT06109025), as well as starting sample collection. It will run for two months. As the sample is collected, it will be randomised and assigned to the different groups.

Data collection phase: This is the longest phase of all and is spread over 13 weeks. During these weeks, pre-intervention assessments, interventions, as well as post-intervention assessments and follow-up assessments two weeks after leaving the intervention will be carried out. The assessments were carried out by blinded evaluators who did not know the assigned group. All the groups will receive the intervention in the non-dominant arm.

a) Control group: This group will not receive any type of intervention and will continue with their usual routine. They will be asked to commit not to start any physical activity other than the one they have already done for the duration of the study.

b) Selective FES (Fesia Grasp) group: 5 sessions of 30 minutes will be carried out, and the 2 available protocols will be used: “habituation” and “repetitive task training”.

- Protocol 1: Habituation: This will be used during the first half of the first session so that the participant gets used to the sensation of electrical stimulation by means of an automatic sweep of electrical stimulation.

- Protocol 2: Repetitive task training: To be used in sessions 1-5 inclusive. Firstly, the device will be configured, selecting the cathode combinations that generate the clearest flexion and extension movements of the wrist, thumb, index and fingers 3, 4 and 5. If the motor threshold for any of the movements is not found in any of the users, or it is considered that it may be harmful or not beneficial to stimulate any of these movements, it will not be selected. It will be important to carry out this configuration thoroughly in the first session, and small variations will be made in subsequent sessions. The therapy will then be initiated. This will progress as follows (to be adjusted according to the progress of the patients):

- Sessions 1-3: selective contractions of the muscle groups of the forearm. The general progression proposed for sessions 1-3 is as follows: Beginning (5 minutes): placing the device and checking that the previous configuration is correct. First part (5 minutes): selective contractions of the different muscle groups using FES. Second part (10-15 minutes): voluntary selective contractions by the patient, guided by the therapist.
- Sessions 4-5: training of activities of daily living with the help of FES. The general development proposed is as follows: Beginning (5 minutes): setting up the device and checking that the previous configuration is correct. First part (5 minutes): selective contractions of the different muscle groups using FES. Second part (10-15 minutes): inclusion of the previously activated functional movements in functional actions using

FES: grasping objects of different sizes.

C) Traditional FES (Globus Elite electro stimulator) group: 5 sessions of 30 minutes duration will also be carried out. The device will be applied in the following way (it will be adjusted according to the progress of the patients):

- Sessions 1-3: general repetitive contractions of the muscle groups of the forearm. The general sequence is as follows: Beginning (5 minutes): placing the device and checking that the configuration is correct. First part (5 minutes): general contractions of the different muscle groups using FES. Second part (10-15 minutes): general voluntary contractions by the patient, guided by the therapist.
- Sessions 4-5: training of daily living activities with the help of FES. The general development proposed during sessions 4-5 is as follows: Beginning (5 minutes): setting up the device and checking that the configuration is correct. First part (5 minutes): general contractions of the different muscle groups using FES. Second part (10-15 minutes): inclusion of the previously activated functional movements in functional actions using FES: grasping objects of different sizes.

The electro-parameters selected will be the same in both FES groups (frequency: 25 Hz; pulse-width: 250 μ s). Therapy times will vary according to the patient's fatigue as measured by a Borg scale. The Borg scale score should not exceed 3 points out of 10 ($\leq 3/10$), 1 minute after the end of the exercise. If the perception of fatigue is higher, first the intensity (e.g. frequency of movements) and then the duration of therapy will be adjusted.

d) Virtual Rehab Hands Group: The group will play for 5 sessions of 30 minutes. The Virtual Rehab Hands device includes fine motor games thanks to an ergonomic support to rest the arm and to be able to perform the exercises more comfortably with the Leap Motion® sensor that accurately detects the movements of the hands, fingers and wrists. The session will be divided into three phases: warm-up, effort and cool-down.

- In the warm-up phase we will play "wrist flexion and extension bird"; "flexion and extension candy"; "ulnar-radial deviation frog"; and "ulnar-radial deviation frog".
- In the effort phase: "digital piano"; "balloon tongs"; "finger abduction".
- In the return to bed phase: "frog flexion-extension"; "wrist flexion and extension bird"

Measurement tools

Different assessment tools have been developed that assess hand dexterity, strength and MI:

- Nine Hole Peg Test: This test is included for the assessment of manual dexterity. Nine Hole Peg Test (NHPT) [16], consists of a manual test, in which the subject must place 9 pegs in their corresponding 9 holes, and remove them again, the variable measured being the time it takes to carry out the whole process. Less time, implies better manual dexterity.
- Box and Block Test: consists of a rectangular wooden box with a base 53.7 cm wide and 25.4 cm long, which is divided into two square compartments of 25.4 cm on each side separated by a 15.2 cm high separator. The test contains 150 cube-shaped wooden blocks of 2.5 cm on each side. The number of blocks the subject has carried from one compartment to another with each hand in one minute of time is to be recorded. Higher scores indicate better manipulative skills.
- Hand grip strength (Jamar hand dynamometer): This dynamometer is used to measure grip strength in the hand, allowing the force exerted by the individual to be converted into a numerical reading. The subject is asked to grip the device and is instructed to perform the

maximum sustained contraction. The force is recorded in kilograms.

- **Timing:** The assessment of MI ability requires at least two tests. Chronometry is defined as the temporal congruence between an executed motor act and the same imagined act. In this case, the NHPT itself is proposed as the executed motor act. So, once administered to obtain the test variable (time taken to perform), the participant will be asked to imagine the performance of the test, and it will be timed. Both measurements will be taken in seconds, to calculate the chronometric ratio (CR), according to the formula [17]: $CR = (\text{Time motor act executed} - \text{Time motor act imagined}) / \text{Time motor act executed}$.
- **Movement imagery Questionnaire, revised (MIQ-RS):** The MIQ-RS questionnaire [18] consists of 2 subscales, one visual and one kinaesthetic, of 7 items each, each item being scored on a 7-point Likert scale (the higher the score, the greater the ease of imagining). For all items, the user is asked to perform a certain motor act (only once), to return to the starting position, and then to imagine it. When scoring the visual scale, the participant is asked to generate an image "as if they could see themselves" doing the gesture, while the kinaesthetic scale asks them to "recall the sensation of the movement". The minimum values are 14, and the maximum values are 98 (minimum 7 and maximum 49 for the subscales). The Spanish version of the MIQ-RS has been validated by [19] in a sample of university students, obtaining Cronbach's Alpha values of 0.90 and a two-factor structure.

Several devices will be used to carry out the intervention, including the following:

- **Fesia Grasp:** This device bases its operation on superficial electrical stimulation of the antebrachial musculature to generate flexion and extension movements of the wrist, thumb, index finger and fingers 3, 4 and 5. The device is CE marked. The main feature of this device is its multi-field electrode, which allows a greater number of movements to be selected, to do so quickly and selectively, and to combine the movements with each other. This is a matrix electrode designed to cover a large part of the surface of the forearm in order to stimulate the muscles of the neuro-muscular groups of the radial, ulnar and median nerves. It is composed of 32 cathodes (output fields) and 8 anodes (return fields), which can be activated independently or in combination, allowing it to be adapted to the anthropometry of different patients.
- **Globus Elite 4-channel electrostimulation:** This is a traditional electrical stimulation device, which allows up to 8 electrodes to be activated at the same time (4 channels). The device, which is CE marked, allows the use of different types of electrical currents, which are selected according to the desired therapeutic objectives and the evolutionary phase of the person. Among the currents that can be applied are the currents also emitted by the Fesia Grasp device. These currents are biphasic and symmetrical rectangular.
- **VirtualRehab for hand:** VirtualRehab is a therapeutic physical rehabilitation tool that uses VR to provide therapy for patients with neurological or musculoskeletal disorders; providing a wide range of activities designed to improve mobility, coordination and strength. This tool is based on the idea of gamification in rehabilitation, where patients participate in virtual games that require physical movements to complete challenges. These games are adapted to the needs and abilities of each patient, allowing for personalised rehabilitation. VirtualRehab allows for: a) a comprehensive assessment; b) personalised treatment planning; c) monitoring and tracking of patients' progress. This tool has different

fine motor games, including 8 video games for fine motor training that can be customised to the needs of each patient.

Ethical considerations

The study has been approved by the Ethic Committee of Burgos University (IO 2/2023). It will be conducted according to Helsinki declaration, and the requirements established in Spanish legislation. All participants will be informed previous their participation, and all of them will sign the informed consent form before the evaluation. The data will be anonymised.

The study is registered in Clinical Trial: NCT06109025.

Dissemination plan

Once the study is completed, it is planned to publish the results in high impact journals, preferably in open access. In addition, we will participate in at least two specialized congresses, through oral communications and/or posters.

Statistical analysis

The SPSS V 28 software shall be used for all analyses.

General analysis

Comparative analyses between the four groups will be carried out in order to verify that there are no differences between groups at the beginning of the different interventions (ANOVA analysis for baseline). Also, descriptive analysis of the sample will be carried out.

Inferential analysis

The two-way repeated measures ANOVA (group \times time), with post-hoc and Bonferroni analyses, will be used to test the hypotheses despite the fact that the sample does not meet the normality criteria [20].

Repeated measures ANOVA analyses will also be performed, the use of the repeated measures procedure provides a more effective control of extraneous sources of variation associated with individual characteristics; i.e., a reduction in error variance is achieved [21].

Discussion

This study aims to compare the effectiveness of the selective FES training, traditional FES training and virtual reality (VR) to improve MI parameters, strength and manual dexterity in upper extremities of healthy subjects. For this, 4 groups will be created (selective FES, traditional FES, VR and control) and the following pre- and post-treatment measurements will be carried out: NHPT, Box and Block Test, hand grip strength and MIQ-RS.

One of the most common sequelae after stroke or other neurological diseases is the limitation or loss of functional capacity of the upper extremities [22]. Around 65% of the affected people are unable to use their affected limb in daily living activities 6 months after the impairment [23], and this loss of functionality directly affects quality of life, making them, in many cases, dependent [24].

Motor imagery is one of the key factors when rehabilitating the affected limb, which allows it to be trained even in situations in which the motor skills of the limb are practically non-existent [25]. In order to carry out interventions based on MI it is necessary that the person who is going to receive the treatment has a certain facility to imagine these motor acts. This is not always the case, and it is necessary to improve their MI skills so that they can benefit as much as possible from MI-based treatment. Although there are various techniques that have demonstrated good results when it comes

to improving MI (mirror therapy, for example) [26], more effective and easy-to-use techniques are necessary.

On the one hand, VR has proven to be effective in increasing patient motivation enhancing adherence to treatment [27]. If the results in terms of MI improvement were also positive, it could become a technique of choice in people with severely affected limbs in whom following traditional MI treatment is complicated, because of the lack of usability.

On the other hand, electrical stimulation is one of the therapies that has a higher level of evidence for the motor rehabilitation of the upper extremity in people with neurological pathology [28]. However, its effect on MI parameters is still unknown, as there are few studies in this regard. However, the findings in neuroplasticity parameters suggest that it could be an interesting technique for this [27].

Furthermore, if this FES is applied selectively using multi-field electrodes, the effects could be even greater, since it would facilitate focusing the sensory input (central and peripheral) on those affected muscles and brain or spinal areas, giving the minimum stimulus necessary to the execution of certain motor tasks [29]. In addition to increasing clinical effectiveness, the use of multi-field electrodes has been shown to increase the usability of FES systems [30], which could also have an effect on patient motivation and treatment adherence. If the study demonstrates that FES interventions improve MI, it may be an interesting alternative to improve this skill before starting treatment based on imagination, and at the same time improve some of the skills such as strength or manual dexterity.

If this study provides positive results, it would be interesting to test it in persons with neurological impairments, such as stroke or spinal cord injury, to observe if it would be effective to recommend that these techniques be implemented in treatment protocols for patients with motor disorders due to neurological diseases, and to justify new cost-effectiveness studies.

Conflicts of Interest

A.M.-O work for Fesia Technology, from which they receive financial compensation. Fesia Technology has participated in the development of the device used in the study.

The rest of the authors declare that they have no conflict of interest.

Abbreviations

CR: chronometric ratio

FES: functional electrical stimulation

MI: Motor imagery

MIQ-RS: Movement imagery Questionnaire revised

NHPT: Nine Hole Peg Test

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