UNIVERSIDAD DE BURGOS

A/A of the President of the Commission
Bioethics of the University of Burgos

Report request to the Bioethics Commission

Mr. MONTSERRAT SANTAMARÍA VÁZQUEZ, with ID 13156556G, and contact telephone number 630569820.

EXPOSES:

What does the project titled: IMPROVEMENT OF THE CAPACITY OF MOTOR IMAGINATION THROUGH FUNCTIONAL ELECTRICAL STIMULATION

Project report is attached for your evaluation.

Project memory:

Researchers: Montserrat Santamaría Vázquez Juan Hilario Ortiz Huerta Olalla Saiz Vazquez Aitor Martín Odriozola	
Type of work: Research work.	
Title IMPROVEMENT OF THE CAPACITY OF MOTOR IMAGINATION AND MANUAL WEEDING, THROUGH ELECTRICAL STIMULATION FUNCTIONAL	

1.- Introduction/Justification

Motor imagination (MI) is defined as the cognitive process of imagining the movement of a part of a person's own body without actually moving that part of the body (Al-Saegh et al.,2021).

IM training in healthy adults has been shown to improve strength, arm positioning speed, and joint range (Dickstein and Deutsch, 2007). On the other hand, the capacity of MI has been shown to be related to proprioception. Shenton et al (2004) have suggested that proprioception, in some circumstances, may represent an important input at the sensory level that contributes to the representation of the body; Furthermore, McCormick et al (2007) have suggested that altered proprioceptive input could alter MI tasks.

The research question of this work is based on seeing if the relationship between IM and the aforementioned parameters also occurs the other way around. Could improving strength and/or manual dexterity also improve IM?

Neuromuscular electrical stimulation *(NMES)* is an application of electrical stimulation used in movement rehabilitation Stein et al

(1992). Functional electrical stimulation *(FES)* is a subtype of NMES in which stimulation supports functional and purposeful movements Popovic et al (2001). This technique consists of applying electrical currents to the muscles, making them contract in a sequence that allows you to perform different tasks. Some of the examples are: holding a key, holding a toothbrush, standing or walking Vodovnik et al (1978).

The technology was developed in the 1960s, during which initial clinical use began, emphasizing its potential as an assistive device Hoshimiya et al (1989). Since then, FES has evolved into an important therapeutic intervention that rehabilitators can use to help people with diseases or injuries to the nervous system regain their ability to stand, walk, reach and grasp Buckett et al (1988) , having demonstrated positive effects in

increased muscle strength, remission of osteopenia and improved walking (Bélanger et al, 2000; Sabut, 2011).

FES device technology has traditionally been based on conventional electrodes. However, multi-field surface electrodes have emerged, consisting of groups of several small conductive fields, which can be activated/deactivated and configured independently (FesiaGrasp, 2022).

The Fesia Grasp system is a FES-based neurological hand rehabilitation device developed by Fesia Technology (Donostia-San Sebastián, Spain). This is a commercial device designed for manual dexterity rehabilitation, which delivers a train of biphasic pulses of different widths and amplitudes to different electrode fields asynchronously, meaning that different electrode fields are activated with an interval predefined between pulses Maleševiÿ et al (2017).

Fesia Grasp, generates superficial electrical stimulation of the forearm muscles to trigger eight different flexion and extension movements of the wrist and fingers in order to restore the function, freedom and independence of the patient's hand after a stroke, Martin -Odriozola et al (2021).

The study aims to answer the PICO research question:
Q: healthy adults
I: FES and, multifield FES.
C: video games
O: Motor imagination, strength, manual dexterity.

The aim is to compare different tools in a population sector to check if there is an improvement in motor skills through the use of FES.

2.- Objectives

General objective:

- Check the effects of FES and virtual reality regarding motor imagination, strength and manual dexterity.

Secondary objectives:

- Find out if functional electrical stimulation improves motor imagination, both kinesthetic and visual, as well as manual dexterity and strength.
- Find out if an intervention based on the use of virtual reality improves motor imagination, both kinesthetic and visual, as well as manual dexterity.
- Check if there are differences between FES, multi-field FES, and virtual reality in terms of visual motor imagination, kinesthetic and manual dexterity.

3.- Project description

The present work is a clinical, randomized study of parallel groups of a quasi-experimental type.

A sample of university students will be divided into 4 groups, where one of them will act as a control group (without intervention), and the other three will perform hand training with two different types of FES devices (conventional and multi-field). and a last group will receive hands-on training with video games.
Intergroup analyzes will be performed before the start of training (pre-intervention), after finishing the program (post-intervention), and three weeks after finishing (follow-up evaluation). Likewise, intragroup analyzes will be carried out to check whether the training has caused an improvement in the quality of motor imagination, as well as an improvement in manual dexterity in each of the groups.

To carry out the project, a collaboration agreement will be signed with the company FESIA TECHNOLOGY SL, which will provide a FESIA GRASP device for the study, as well as the consumables (electrodes) necessary for the development of the study. The agreement is currently being evaluated by the UBU legal office.
It is planned to register the study on the international platform Clinicaltrials.gov.

4.- Material and methods

4.1 Type of study

Controlled, randomized, parallel group clinical trial. Unicentric, and with blind evaluation by third parties. Quasi-experimental.

4.2. Description of devices

Four parallel groups are planned. A first group that will have an intervention based on multi-field FES with the FESIA GRASP device; another group that will receive only FES

with the Globus Elite electrostimulation device (device with conventional electrodes); a third group that will receive an intervention based on virtual reality; and finally a control group, which will not receive any treatment.

The three devices are described below.

4.2.1. Description of the FESIA GRASP

The Fesia Grasp device bases its operation on superficial electrical stimulation of the antebrachial muscles to provoke flexion and extension movements of the wrist, thumb, index and fingers 3, 4 and 5. The device has the CE marking.

The main feature of this device is its multi-field electrode, which allows a greater number of movements to be selected, doing so quickly and selectively, and it is also possible to combine the movements with each other. The device is composed of a stimulator, a multi-field electrode, a textile band and a software application. The stimulator generates electrical pulses, which are transmitted to the skin through the multi-field electrode. It is a matrix electrode designed to cover a large part of the surface of the forearm and thus be able to stimulate the muscles of the neuromuscular 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 combined, allowing it to be adapted to the anthropometry of different patients. The multi-field electrode is personal and disposable, with an estimated life of two weeks of daily use.

The textile band ensures correct contact of the electrode with the skin and, on the other hand, serves as a support for both the stimulator and the electrode. The device allows the generation of 8 different isolated movements (flexion and extension of the wrist, thumb, index and fingers 3, 4 and 5). Furthermore, it is possible to combine these movements with each other, with the aim of creating functional movements such as: clamp, lateral clamp, palmar grip, etc.

Finally, Fesia Grasp has a software application on a tablet that allows, on the one hand, to control and configure the stimulation parameters and, on the other, to monitor the evolution of the different patients/users in an easy and intuitive way. The application is FesiaPro, and is designed to be used by healthcare personnel.

4.2.2. Description of the Globus Elite 4-Channel Electrostimulator The

Globus Elite 4-Channel Electrostimulator is a traditional electrical stimulation device, which allows up to 8 electrodes to be activated at the same time (4 channels). The device, which has a CE marking, allows the use of different types of electrical currents, which are selected based on the desired therapeutic objectives and the evolutionary phase of the person.

Among the currents that can be applied are the currents that the Fesia Grasp device also emits. These are currents with a biphasic and symmetrical rectangular pulse shape, low frequencies, constant pulse widths and high intensities.

4.2.3. Description of the VirtualRehab video game for hand

VirtualRehab is a therapeutic physical rehabilitation tool that uses reality

virtual to provide therapy to 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 adapt to the needs and abilities of each patient, allowing personalized rehabilitation.

VirtualRehab allows: a) a comprehensive evaluation; b) personalized treatment planning; c) monitoring and tracking patient progress. This tool has different fine motor games, specifically it includes 8 video games for fine motor training that can be customized for the needs of each patient.

4.3 Sample

The sample will be composed mainly, although not exclusively, of adults of legal age, belonging to the group of university students.

4.3.1. Type of sampling and access to the sample

Participation in the study will be proposed to students of the Faculty of Health Sciences of the University of Burgos, so it is a convenience sampling.
The sample will be randomized through a computer application for assignment within one of the groups contemplated in the study.

4.3.2. Inclusion and exclusion criteria

The following inclusion criteria are established:

a) Be of legal age and sign the informed consent.
b) Not suffer from any pathology in the upper limb such as tendinitis, edema, fractures, etc.
c) Intact skin (no breaks, scratches, cuts, and other types of superficial or deep injuries) on the arm where the devices will be placed if applicable.

As exclusion criteria:

a) Severe medical problems.
b) Use a pacemaker.
c) Being pregnant.
d) Peripheral neuropathies.
e) Presence of other neuromuscular pathologies

Participants may leave the study in the following cases:

a) At your own request, without giving reasons.
b) Adverse events occur that prevent the study from continuing.
c) Non-compliance with treatment. Failure to complete sessions on schedule for each one.

The reason for abandonment will be recorded in the database.

A sample of between 20-25 subjects per group is expected.

4.4 Process

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

4.4.1. Preparation phase:

This phase includes writing the project, obtaining approval from the ethics committee of the University of Burgos, registering it on the Clinicaltrials.gov platform, as well as beginning to collect the sample.

It will run during the months of June-July and the first week of September 2023.
As the sample is obtained, it will be randomized and assigned to the different groups.

4.4.2. Data collection phase

It is the longest phase of all and extends over 13 weeks during the months of September to December 2023. Throughout these weeks, pre-intervention evaluations, interventions, as well as post-intervention evaluations will be carried out. -intervention and follow-up evaluations two weeks after leaving the intervention.

In Figure 1 you can see the distribution for each of the weeks. The Friday before starting the intervention, the subjects will be evaluated (PRE-intervention Evaluation). During the 5 days, the corresponding interventions will be carried out the following week, and at the end of the 5th session they will be evaluated (POST-intervention Evaluation), and two weeks later they will be evaluated again in the follow-up evaluation (SEG Evaluation).

	MONDAY TUESDAY WEDNESDAY THURSDAY	FRIDAY
WEEK 1		PRE 1 Evaluation
		PRE 2 Evaluation
WEEK 2	Intervention 1	POST 1 Evaluation
		PRE 3 Assessment
	Intervention 2	POST 2 Evaluation
WEEK 3		
		PRE 4 Assessment
	Intervention 3	POST 3 Evaluation
WEEK 4		SEG 1 Evaluation
		PRE 5 Assessment
WEEK 5	Intervention 4	POST 4 Evaluation

		SEG 2 Evaluation
		PRE 5 Assessment
	Intervention 5	POST evaluation
WEEK 6		SEG 3 Evaluation
		PRE 7 Assessment
	Intervention 6	POST 6 Evaluation
WEEK7		SEG 4 Assessment
		PRE 8 Evaluation
	Intervention 7	POST evaluation
WEEK 8		SEG 5 Evaluation
		PRE 9 Assessment
	Intervention 8	POST 8 Evaluation
WEEK 9		SEG 6 Assessment
		PRE 10 Evaluation
	Intervention 9	POST 9 Evaluation
WEEK 10		SEG 7 Evaluation
	Intervention 10	POST 10 Assessment
WEEK 11		SEG 8 Evaluation
WEEK 12		SEG 9 Evaluation
WEEK 13		SEG 10 Evaluation

Figure 1. Timeline of the data collection phase.

4.4.3. Analysis and Reporting

This phase will take place between the final weeks of December 2023 and throughout January-February 2024.

4.5. Evaluation instruments

The following evaluation tools are proposed:

4.5.1. Nine Hole Peg Test:

This test is included to assess manual dexterity.

The Nine Hole Peg Test (NHPT) (Mathiowetz et al, 1985) consists of a manual test, in which the subject must place 9 pegs in their corresponding 9 holes, and remove them again, the measured variable being the time It takes time to complete the entire process.

4.5.2. Box and Block: The

Box and Block test is a tool with standardized dimensions and materials.

It is specified that the subject must sit in front of a rectangular box with his hands next to it. This box is made of wood with a base 53.7 cm wide and 25.4 cm long; This is divided into two square compartments with a side of 25.4 cm each, separated from each other by a 15.2 cm high divider; Both compartments are padded in order to reduce noise during testing. The test contains 150 cubic-shaped wooden blocks measuring 2.5 cm on each side. The number of blocks that the subject has transported from one compartment to another with each hand in one minute of time must be recorded.

Higher scores indicate better manipulative skill.

4.5.3 Jamar hand dynamometer

The Jamar hand dynamometer is used to measure grip strength in the hand, it allows the force exerted by the individual to be converted into a numerical reading. The subject is asked to grasp the device and is instructed to perform the maximum sustained contraction. The force is recorded in kilograms.

4.5.2 Chronometry:

The evaluation of motor imagination capacity 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 motor act executed. So once administered to obtain the test's own variable (time taken to perform), the participant will be asked to imagine performing the test, and it will be timed. Both measurements will be taken in seconds, to calculate the chronometric ratio, according to the formula (Liepert, 2012):

$$Rc = \frac{\text{(Time executed motor act – Time imagined motor act)}}{\text{Time motor act performed}}$$

4.5.3. Movement imagery Questionnaire, revised (MIQ-RS)

The MIQ-RS questionnaire (Gregg et al, 2010) consists of 2 subscales, one visual and the other kinesthetic, with 7 items each, with each item scored on a 7-point Likert scale (the higher the score, the higher the score). ease to imagine). For all items, the user is asked to perform a specific motor act (only once), return to the starting position, and then imagine it. When scoring the visual scale, the participant is asked to generate an image “as if it were seen” by making the gesture, while the kinesthetic scale is asked to “remember the sensation of the movement.”

The administration manual specifies that the visual and kinesthetic items will not be administered consecutively, but rather are altered randomly to avoid bias.

The minimum values are 14, and the maximum values are 98 (minimum 7 and maximum 49 for the subscales).
This MIQ-RS version was made to be administered to a population with some type of physical disability, but it can also be applicable to healthy people. The Spanish version of the MIQ-RS has been validated by Cantalejo-Fernández (2022) in a sample of university students, obtaining Cronbach's Alpha values of 0.90 and a two-factor structure.

4.6. Description of the intervention.
As explained, the study will consist of 4 groups.
Each group will receive a total of 5 sessions (Figure 1). Next, it is explained what each of the 4 groups will do.

4.6.1 Control group: This group will not receive any type of intervention and will continue with their usual routine. A commitment will be requested that they do not begin any physical activity other than that previously carried out for the duration of the study.
4.6.2 FESIA GRASP Group:
There will be 5 30-minute sessions, and the 2 available protocols will be used: training and grip.

Protocol 1: Training: It will be
used during the first half of the first session so that the participant becomes accustomed to the sensation of electrical stimulation through an automatic sweep of
electrical stimulation.
Protocol 2: Grip
It will be used in sessions 1-5, both inclusive. Firstly, the device configuration will be carried out, selecting the combinations of cathodes that generate clearer flexion and extension movements of the wrist, thumb, index and fingers 3, 4 and 5. If the motor threshold is not found in any user for any of the movements, or it is considered that it may be harmful or not beneficial to stimulate any of these, it will not be selected. It will be important to do this setup thoroughly in the first session, and minor variations will be made in subsequent sessions.
Next, the therapy will begin. This will progress as follows (it will be adjusted depending on the patients' progress):

- Sessions 1-3: selective contractions of the forearm muscle groups.
- Weeks 4-5: training in activities of daily living with the help of FES

The general development proposed during sessions 1-3 is as follows:

- Startup (5 minutes): Place the device and verify that the previous configuration is correct.
- First part (5 minutes): selective contractions of the different groups muscles through FES.
- Second part (10-15 minutes): voluntary selective contractions by the

patient, guided by the therapist.

The general development proposed during sessions 4-5 is as follows:

- Startup (5 minutes): placing the device and verifying that the previous configuration is correct.
- First part (5 minutes): selective contractions of the different groups muscles through FES.
- Second part (10-15 minutes): inclusion of functional movements previously activated in functional actions through FES: grasping objects of different sizes.

The selected electro-parameters will be those preconfigured by default in the systems from Fesia, both in the training protocol and in the grip protocol: 25 Hz frequency, 250 us pulse width. The intensity will be 5 mA above the motor threshold, the motor threshold being the minimum intensity at which the movement of the limb is perceived visually. If the patient cannot tolerate such intensity, he will limit himself to the maximum intensity at which this sensation is pleasant.

Therapy times will vary depending on the patient's fatigue measured using a Borg scale. The score for this should not exceed 3 points out of 10 (< = 3/10), 1 minute after the end of the exercise. If the perception of fatigue is greater, first the intensity (eg frequency of movements) and then the duration of the therapy will be adjusted.

4.6.3. Globus Elite Electrostimulator Group:

You will also carry out 5 sessions of 30 minutes duration. The device will be applied in the following way (it will be adjusted depending on the patients' progress):

- Sessions 1-3: general repetitive contractions of the muscle groups of the forearm.
- Weeks 4-5: training in activities of daily living with the help of FES

The general development proposed during sessions 1-3 is as follows:

- Startup (5 minutes): Place the device and verify that the configuration is correct.
- First part (5 minutes): general contractions of the different groups muscles through FES.
- Second part (10-15 minutes): general voluntary contractions by the patient, guided by the therapist.

The general development proposed during sessions 4-5 is as follows:

- Startup (5 minutes): Place the device and verify that the • configuration is correct.

- First part (5 minutes): general contractions of the different groups muscles through FES.
- Second part (10-15 minutes): inclusion of functional movements previously activated in functional actions through FES: grasping objects of different sizes.

The electro-parameters selected will be the same as those used in the previous group.

Therapy times will vary depending on the patient's fatigue measured using a Borg scale. The score for this should not exceed 3 points out of 10 (< = 3/10), 1 minute after the end of the exercise. If the perception of fatigue is greater, first the intensity (eg frequency of movements) and then the duration of the therapy will be adjusted.

4.6.4. Rehab Hands Virtual Group

The group will play for 5 30-minute sessions. The Virtual Rehab Hands device includes fine motor games thanks to an ergonomic support to rest the arm and 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 return to calm.

- In the warm-up phase, “wrist flexion and extension bird” will be played; “candy flexion and extension”; “ulnar-radial deviation frog”
- In the effort phase: “digital piano”; “balloon clamps”; “finger abduction”
- In the phase of returning to bed: “flexion-extension frog”; “flexion and extension bird “wrist”.

4.7. List of expected adverse events

During the course of the proposed study, all adverse effects will be registered.

Every effort will be made to remain alert to potential complications and unexpected results. If complications occur, the first concern will be the safety of the participant.

Intensive use of the Fesia Grasp product may entail a series of risks (described below) that will be minimized by taking their respective precautionary measures:

- Electrical stimulation may cause an uncomfortable sensation or very mild pain in the first few uses until you become familiar with the sensation.

- It is normal for the area where the stimulation has been applied to appear red after removing the device; this redness should disappear in approximately one hour.

- In some cases, electrical stimulation or contact of the gel with the skin could cause an allergic reaction or irritation at the contact surface.

The patient must immediately stop using the device in the following cases:

- You have redness or irritation in the stimulation application area for more than one hour after removing the electrode.
- Presents blisters or sores in the stimulation application area.
- You feel cardiac stress or tachycardia during pacing.
- You have swelling of the leg, knee, ankle or foot.

5.- Proposal from the researchers to ensure compliance with legal and ethical aspects of the research and the rights of the participants

In this study, clinical research is carried out with health products on people.
In order to safeguard the integrity, well-being and right to privacy of the participating subjects, the study is carried out following the standards dictated by the Declaration of Helsinki of the World Medical Assembly (64th General Assembly, Fortaleza, Brazil, October 2013). , the Council of Europe Convention on human rights and biomedicine, the Standards of Good Clinical Practice, Royal Decree 1090/2015, of December 4, which regulates clinical trials with medicines, the Ethics Committees of Research with medicines and the Spanish Registry of Clinical Studies and Royal Decree 1591/2009, of October 16, which regulates health products.

Before the beginning of the study, explicit informed consent will be requested from participants, through an online form in which the objectives and what their participation consists of will be explained (Annex 1).

Compliance with Organic Law 3/2018, of December 5, on the Protection of Personal Data and guarantee of digital rights, will be ensured.

The privacy of the participants will be protected and the exclusive use of the data collected for the purposes of the project and those studies that may result from it will be guaranteed.

6.- Determination of the potential benefits and risks of the study

The participation of the subjects in this project implies the eventual possibility of suffering adverse effects, none of which seriously compromise the integrity of the subject. Every effort will be made to remain alert to potential complications and unexpected results. If complications occur, the first concern will be patient safety.

The intensive use of FES can entail a series of risks (described below) that will be minimized by taking their respective precautionary measures:

- Electrical stimulation may cause an uncomfortable sensation or very mild pain in the first few uses until you become familiar with the sensation.
- It is normal for the area where the stimulation has been applied to appear red after removing the device; this redness should disappear in approximately one hour.
- In some cases, electrical stimulation or contact of the gel with the skin could cause an allergic reaction or irritation at the contact surface.

The patient must immediately stop using the device in the following cases:

- There is redness or irritation in the stimulation application area during more than one hour after removing the electrode.
- Presents blisters or sores in the stimulation application area.
- You feel a significant increase in muscle spasticity.
- You feel cardiac stress or tachycardia during pacing.
- Presents swelling in the extremity.

Regarding the collection of data on motor function, this is carried out using non-invasive techniques so they do not pose any risk to the participant.

The benefits that the subject obtains in this project are the motor improvement and functionality of the upper limb, as well as a direct contribution to the advancement of knowledge of new techniques or therapies for their pathology.

7.- Information and informed consent document, if applicable

All participants will be sent an information document and a informed consent, where the entire study that is going to be carried out and what data will be used will be explained to them. It is attached as annex 1.

8.- Compensation provisions for participants, if applicable

Not applicable.

9.- Coverage in case of damage due to participation, if applicable

The device is sufficiently safe, the sample corresponds to healthy subjects, and no

contemplates the possibility of generating any type of damage.

10.- Description of the data analysis and the statistical study required, if applicable

The characteristics between groups will be analyzed before the start to confirm that there are no differences between them before the start of the intervention.

Subsequently, intra-group analysis will be done to see the effects on each of them, as well as inter-group analysis to see if there are differences between the different interventions. These intra-group and inter-group analyzes will be done with respect to the baseline and follow-up measurement.

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12.- In the event that the research project involves the processing of personal data, complete the following sections1

12.1.- Type of personal data that will be processed (identification, social, academic, professional, economic and financial...)

Basic identification and social data will be collected that will be used to describe the sample, according to the principle of minimization, and own data derived from the tests administered will be collected.

12.2.- If they are special categories of data (health, biometric, genetic...). Indicate which category they belong to.

The data is not considered to belong to any special data characteristic.

1 To cover this section, it is recommended to read the FAQ_Guide document beforehand. Researcher (link)

12.3.- Indicate the group from which the data is collected (adults, children under 14 years of age, people with illness, functional diversity or physical/mental disability.

Adults. University students.

12.4.- Indicate how the data will be collected (interviews, surveys, forms, Internet, etc.).

The data will be collected through a clinical interview and the administration of the tests in person.

12.5.- Indicate whether the data are going to be anonymized (it is not possible to identify the persons) or pseudo-anonymized (a non-identifying or identifiable code is assigned to each subject, so that subsequent identification would be possible).

The data will be pseudonymised. A non-identifying, non-identifiable code is assigned to each subject, so that subsequent identification would be possible.

12.6.- In case of anonymization or pseudonymization, indicate the techniques used.

The data will be dissociated to the extent possible.

- The researchers will only have access to the personal data of the participants in the informed consent document. The signed document will be a paper file, which will be kept in a locked cabinet within the UBU facilities.

- Once the project has started, only the main researcher will have access to the identifying data of the participants.
- The data collected in the interviews and test administration will be transferred to an Excel document, to which only the project researchers will have access.

- Data from the pre/post intervention and follow-up interviews will be included in Excel, where each participant will be assigned an anonymous participation code that allows the linking of pre-post intervention and follow-up results.

- The anonymous participation code will not allow the identification of participants: It will be composed of the first letter of the first name and the last of the surnames. This will be followed by a hyphen and the figure resulting from adding the day and month of data collection. For example, if the interviewer's name is Montserrat Santamaría Vázquez, and she conducted the interview on May 12, her code will be: MAZ-17

12.7.- If applicable, indicate if several organizations or partners participate in the project.

A collaboration agreement will be signed with the company FESIA TECHNOLOGY SL, for the transfer of the FESIA GRASP device.

12.8.- Duration of data processing. Period of conservation/deletion of data at the conclusion of the investigation and place of conservation.

The databases will be kept throughout the life of the project and at least during the three subsequent years in order to ensure the processing of data for exclusive purposes research. The storage location for the information will be One Drive (package of Office 365) from the University of Burgos; Therefore, the information will be hosted in the servers of said University.

12.9.- Indicate if the purpose of the treatment is:

ÿ Create personal profiles.
ÿ Process data on a large scale.
ÿTreat special categories of data.
X ÿ **Monitoring, control and observation of people (monitoring).**
ÿUse technologies that may be especially intrusive, electronic surveillance, data mining, biometrics, genetic techniques, geolocation.
ÿYou process data related to the observation of public access areas.

12.10.- Is the international transfer of data outside the European Union foreseen?

No.

12.11.- Will data be communicated or transferred to third parties?

If a scientific publication were derived from the work carried out, the database (without the possibility of identifying the subject) would be shared in open access databases, in addition to presenting the possible results in the content of the article.

12.12.- Is the reuse of personal data for research purposes planned?

No. It is not planned to contact the subjects again once this project ends.

12.13.- Briefly indicate the technical and organizational measures that will be taken with respect to data processing (pseudonymization, access control and registration, data encryption or coding...).

Some of these measures have already been mentioned in previous sections. Next, they appear again collected:

- Each participant will be given a non-identifiable code, with the following formula: The anonymous participation code will not allow the identification of the participants: it will be composed of the first letter of the first name and the last of the surnames. This will be followed by a dash and the figure resulting from adding the day and month from the day of signing the informed consent. For example, if your name is Montserrat Santamaría Vázquez, and you conducted the interview on May 12, your code will be: MAZ-17

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- Informed consents, where identifying data appear, are
  They will be kept under lock and key, in paper format, in the facilities of the Faculty of Health Sciences, and only the principal investigator will have access.
- Digital files derived from research, such as databases and
  others will be hosted on the OneDrive Platform (Office 365), with limited access to project researchers.

12.14.- Indicate other aspects that you consider relevant regarding data protection.

Participation will be free and there will be no type of benefit to participants.

Contact information for the person responsible will be provided to clarify any doubts that may arise regarding the process.

REQUEST:

The favorable report from the Bioethics Commission of the University of Burgos to carry out the previously referenced project.

Burgos on June 26, 2023.

Signed: Montserrat Santamaría Vázquez

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PARTICIPANT INFORMATION SHEET

PROJECT TITLE: Improvement of motor imagination capacity and manual dexterity through functional electrical stimulation

PRINCIPAL INVESTIGATOR: Dr. Montserrat Santamaría Vázquez
CONTACT PHONE: 630 56 98 20. **EMAIL:** msvazquez@ubu.es

INTRODUCTION

We are writing to you to invite you to participate in the study "Improvement of motor imagination capacity and manual dexterity through functional electrical stimulation", which has been approved by a Bioethics Committee of the University of Burgos. The promoter of the study is the University of Burgos and it is a study with a low level of intervention (BNI) since it uses techniques widely used in the usual practice of numerous centers for many years.

Our intention is that you receive correct and sufficient information so that you can evaluate and judge whether or not you want to participate in this study. To do this, read this information sheet carefully. We will inform you and clarify any doubts that may arise after the researcher's explanation. In addition, you can consult with the people you consider appropriate.

VOLUNTARY PARTICIPATION

You should know that your participation in this study is voluntary and that you can decide not to participate or change your decision and withdraw your consent at any time, without altering your relationship with your academic staff or causing any harm to the treatment you receive. gives.

If you decide to abandon the study, you can do so by allowing the use of the data obtained so far or, if you wish, your data will be deleted from the computer files. You may also be withdrawn from the study if at any time any type of intolerance or discomfort related to the intervention is detected.

THE PURPOSE OF THE STUDY

To check the effects of functional electrical stimulation (FES) and virtual reality regarding motor imagination, strength and manual dexterity.

STUDY DESCRIPTION

The project is a clinical study with a medical product within the framework of collaboration between the University of Burgos (UBU) and Fesia Technology. The objective of this study is to verify the effects of functional electrical stimulation and virtual reality on motor imagination, strength and manual dexterity. The study will be carried out following the following methodology:

The planned duration of the study is 1 week and a total of between 80 and 100 people will be recruited. On the first day, an initial physical evaluation will be performed to assess the motor and functional status of the upper limb.

You will be randomly assigned to one of the 4 groups in this study:

- Group 1: This group will not receive any type of intervention and will continue with their usual routine. A commitment will be requested that they do not begin any physical activity other than that previously carried out, for the duration of the study.
- Group 2: Five 30-minute sessions of electrical stimulation will be performed on the forearm muscles using selective movements provided by the Fesia Grasp device.
- Group 3: Five 30-minute sessions of electrical stimulation will be performed on the forearm muscles using general movements provided by the 4-channel Globus Elite device.
- Group 4: 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 be able to perform the exercises more comfortably with the Leap Motion® sensor that accurately detects the movements of the hands, fingers and dolls.

At the end of the intervention, the clinical examination will be repeated. These assessments will be repeated 2 weeks after completing the intervention.

The type of intervention you will receive is assigned at random, that is, neither you nor the researchers who evaluate you will know which group you belong to. This procedure is very necessary for the results of the study to be valid.

An average of 5 application sessions will be applied using electrical stimulation, virtual reality in your upper extremity. These sessions will be done 5 times a week for 1 week. If you belong to the control group, no technique will be applied. In addition, assessments of hand function will be carried out before, after and after 2 weeks of the protocol.

It is important to emphasize that you will not receive any type of drug during your participation.
If modifications are necessary throughout the study, you will be notified in advance.

The research team that will access your data on behalf of the person responsible for the file is made up of:

- Montserrat Santamaría Vázquez.
- Juan Hilario Ortiz Huerta.
- Olalla Saiz Vázquez.
- Aitor Martín Odriozola.

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WHAT YOUR PARTICIPATION CONSISTS OF

An average of 5 application sessions will be applied using electrical stimulation, virtual reality in your upper extremity. These sessions will be done 5 times a week for 1 week. If you belong to the control group, no technique will be applied. In addition, assessments of hand function will be carried out before, after and after 2 weeks of the protocol.

It is important to emphasize that you will not receive any type of drug during your participation. If modifications are necessary throughout the study, you will be notified in advance.

FREE WITHDRAWAL

You have the right to withdraw or revoke consent at any time, without giving reasons and without affecting your current or future relationship with your University, or your legal rights. And also that, consequently, no new data will be collected, although the information recorded up to that point cannot be deleted.

BENEFITS, RISKS AND DISCOMFORT ARISING FROM YOUR PARTICIPATION

You are not expected to receive any financial compensation from this study.

Given the characteristics of the study and since it is not a drug study, the risks are minimal. The intensive use of FES can entail a series of risks (described below) that will be minimized by taking their respective precautionary measures:

- Electrical stimulation may cause an uncomfortable sensation or very mild pain in the first few uses until you become familiar with the sensation.
- It is normal for the area where the stimulation has been applied to appear red after removing the device; this redness should disappear in approximately one hour.

- In some cases, electrical stimulation or contact of the gel with the skin could cause an allergic reaction or irritation at the contact surface.

The patient must immediately stop using the device in the following cases:

- There is redness or irritation in the stimulation application area during more than one hour after removing the electrode.
- Presents blisters or sores in the stimulation application area.
- You feel a significant increase in muscle spasticity.
- You feel cardiac stress or tachycardia during pacing.
- Presents swelling in the extremity.

Regarding the collection of data on motor function, this is carried out using non-invasive techniques so they do not pose any risk to the participant.

CONFIDENTIALITY AND USE OF DATA

The information you will provide through the questionnaire will be protected through an encryption process. Each participant's data will be assigned a study code to facilitate the completion of study procedures. Aitor Martín Odriozola, may relate your data, being responsible for safeguarding the consent document, guaranteeing compliance with your will regarding the use of the responses that you provide for research. The data collected will be used only to fulfill the objectives of the study.

Compliance with **Law 14/2007 on Biomedical Research, Organic Law 3/2018 of December 5, on the Protection of Personal Data and Guarantee of Digital Rights is guaranteed** (further information on data protection may be obtained by contacting with the person indicated in the following section), and **Regulation (EU) 2016/679 of the European Parliament and of the Council of April 27, 2016** regarding the protection of natural persons with regard to the processing of personal data and the free circulation of these data and by which Directive 94/46/EC (General Data Protection Regulation) is repealed, especially with regard to the sending and handling of data to third parties, so it will not be used or made public no data that could identify the participants. The results of the study may be disseminated using the usual scientific channels (in no case with data that can identify you).

CONTACT IN CASE OF QUESTIONS

If you have any additional questions about this study and your participation in it, you can contact **Montserrat Santamaría Vázquez,** from the University of Burgos (UBU).

- Telephone: 630 56 98 20.
- Email: msvazquez@ubu.es

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INFORMED CONSENT FORM.

Research project: Improving motor imagination capacity through functional electrical stimulation

Principal Investigator: Dr. Montserrat Santamaría Vázquez

Collaborating Researchers: Juan Hilario Ortiz Huerta, Olalla Saiz Vázquez, Aitor Martin Odriozola

Organization: University of Burgos

Me (name and surname):
……

- I have read the information sheet provided to me and understand the risks and benefits it entails.

- I have been able to ask questions about the study.
- I have received enough information about the study.
- I have spoken with:

……

I understand that participation is voluntary and I will not receive any financial benefit for my participation.

I understand that I can withdraw my consent: 1st Whenever I want. 2º Without having to give explanations. 3º Without this affecting the treatment of me as a student.

I freely give my consent to participate in the study.

Investigator's Signature	**Signature of the Participant/Legal Representative**
Name:	**Name:**
Date:	**Date:**