INFORMED CONSENT TO PARTICIPATE IN TESTING OF A MEDICAL PROTOTYPE

Protocol Title: Analysis of Motor Response During Execution of a Proprioceptive Neuromuscular Facilitation Pattern Through Recording of Biomechanical Variables and Electromyographic Activity in Healthy Persons.

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Volunteer's Name: _____

You are invited to participate in a test of a medical prototype. Before deciding whether or not to participate, you must fully understand each of the following sections. This process is known as informed consent. Feel completely free to ask about any aspect to clarify your doubts regarding this.

Once you have understood the test and if you wish to participate **VOLUNTARILY**, you will then be asked to sign this form of consent and/or assent.

Introduction

Through this document, we extend an invitation for you to voluntarily participate in a clinical research study. This study aims to analyze motor responses in plantar flexor and dorsal muscles of the lower limb during the execution of a basic pattern of proprioceptive neuromuscular facilitation in the upper limb.

The study focuses on the relationship in healthy subjects who do not have any neuromuscular complications. It will involve the recording of joint biomechanical variables of the upper limb, as well as electromyographic activity and muscle contraction. Non-invasive devices such as surface electromyographic activity recording systems and video recording for measuring joint and linear positions and speeds of the limbs will be used. The recorded variables will be processed and modeled as time series, and feature extraction will be performed using spatiotemporal techniques. It is anticipated that sufficient evidence will be accumulated to quantitatively describe the process, distinguishing between the five specific movements, considering both intensity and range of motion, for future use in physical therapy.

Once you are informed about the study and the procedures to be conducted, you will be asked to sign this form to participate in the study. Your decision to participate is voluntary, which means you are free to join or not join the study. You may withdraw your consent at any time.

Test Duration

If you decide to participate, the estimated time for the test is subject to the number of breaks you require, with the total continuous time from setup to the execution of movements and the removal of equipment being less than one hour (45 to 60 minutes). During this time, you will wear the device and are free to sit or take breaks whenever needed; you are not obliged to complete the test duration. If you wish to stop, you may do so at any time.

What Will Happen During the Research Study?

After signing the informed consent, we will verify that you meet all the inclusion criteria, which are:

- Be of legal age between 19 and 30 years.
- Individuals in good physical and mental shape.
- Healthy persons, without any neuromusculoskeletal diseases or a clinical history of these conditions in the past.
- Able to perform guided physical activity.

And that you do not meet any of the exclusion criteria:

- Individuals with any serious cardiovascular condition, with chronic disabling disease, any neuromuscular or musculoskeletal pathology, or suffering from any acute or uncontrolled infectious disease.
- Those who have received any vaccine within the last 48 hours.
- Unable to follow instructions.
- Individuals who have had any recent surgical procedures or have exposed wounds.
- Those who have performed intense physical activity within 12 to 24 hours prior to this study.
- Individuals who have consumed any substances containing alcohol or drugs for at least 12 hours before data collection.
- With a history of neurological and musculoskeletal disorders.

Study Procedures

If you decide to participate in the test, the following steps will be followed:

1. Six surface electrodes (similar to gel patches) will be placed on your right arm's skin (see Figure 1). These patches will be connected with long cables called leads, which in turn are connected to a square box device.
2. You will stand to observe the five positions in which you will be asked to perform hand-wrist movements while keeping your arm extended (see Figure 2).
3. The investigator will count 5 seconds and then ask you to change positions, continuing until you complete the five movements. During this time, your muscle activity will be recorded on a computer.
4. You will have a break, and then steps 2 and 3 will be repeated three times.
5. If you feel strange/uncomfortable/heavy, tell us so that the equipment can be removed.
6. If you feel tired, you may indicate this to take a break.

Figure 1. Top View of Electrode Placement

Figure 2. Hand-Wrist Movements to be Performed with an Extended Arm

Potential Risks

The study involves no risk to you as it consists of a series of low-intensity movements and physical load. You may feel a bit tired at the end of the test. There is no compensation for injuries as the study does not involve any risk to you.

Benefits

This study does not provide direct benefits to you, but if you decide to participate in these tests, you will contribute to the development of better therapeutic strategies for those in need, support

advancements in science related to this field, and contribute to the academic development of students at Tecnológico de Monterrey. This participation aids in the advancement of clinical practice.

Injury Compensation

There is no compensation for injuries because the study does not imply risk for you and to reduce the possible appearance of adverse symptoms, the procedure ends with stretching the arms to reduce fatigue and/or muscle pain.

Is participating in the study voluntary?

Yes. Participating in this research study is your choice. You can decide not to participate or change your mind and withdraw (drop out). There will be no penalty.

The principal investigator or co-investigator may decide to remove you from the study without your consent if you do not follow the procedure instructions.

Cost of participation

There will be no cost for your participation in this study.

Will I be paid to participate in this study?

You will not receive any payment for participating in this study.

Participant Responsibilities

Your responsibilities as a study participant include:

- Providing information about your health status before the study and reporting immediately if you experience any discomfort during its progression.
- Following the instructions of the study leader regarding the procedure.

Confidentiality

All information you provide and that is obtained from the tests will be strictly confidential. Your information will be used strictly for academic and scientific purposes and may be reviewed only by members of the independent ethics committee and regulatory medical authorities.

By signing the consent form, you grant access for the current study and any subsequent research that may be conducted using this information. However, the study leader will take necessary measures to protect your personal information and will not include your name or image in any reports, publications, or future disclosures.

You will not be identified in any of the reports or publications resulting from this study.

YOUR RIGHTS ARE NOT AFFECTED UNDER ANY INFORMATION PROTECTION LAWS.

Voluntary Participation/Withdrawal

Your participation in this protocol is entirely VOLUNTARY, and you may withdraw at any time if you wish. If you choose to withdraw from the experiment before its completion, the data recorded up to that point may still be used by the research team, as previously mentioned, while maintaining confidentiality.

Who can I contact if I have questions about my rights?

Before you sign this document, you should ask about anything you don't understand. The study team will answer your questions before, during, and after the study. If you think your question has not been fully answered or if you do not understand the answer, please continue asking until you are satisfied.

If you have any concerns or complaints about this study or how it is being conducted, please do not hesitate to discuss your concerns with Dr. Rita Q. Fuentes Aguilar who is available to answer your questions at (33) 39476711.

Do not sign this form unless you have had the opportunity to ask questions and have received satisfactory answers to all your questions.

Contact

If you have any questions, comments, or concerns about the project, you can directly contact the following people involved in the project via email:

Dusthon Llorente Vidrio: A00835323@tec.mx

Eduardo Morales Vargas: [Email not provided]

Dr. Rita Q. Fuentes: rita.fuentes@tec.mx

Signatures

Mark with an X if the statement is applicable.

- **I have been informed about the study and had my first discussion with the research staff about this information on (DATE)_____ at time _____.**
- **I have read and understood the information in this informed consent document.**
- **I have had the opportunity to ask questions and all have been answered to my satisfaction.**
- **I voluntarily consent to participate in this study. I do not waive any of my legal rights by signing this consent document.**

Name of the responsible: _____

Signature of the responsible: _____

Name of the participant: _____

Signature of the participant: _____

Witness #1	**Witness #2**
Name: _____	Name: _____
Signature: _____	Signature: _____

**Time is necessary only if information was provided on the same day as consent or if consent and any study-specific activities will occur on the same day.*