**PARTICIPANT INFORMATION DOCUMENT**

**Title of research:** Immediate effect of median nerve mobilization on neural conduction in patients with carpal tunnel syndrome. Randomized clinical trial.

**Principal Investigator:** Elena Bueno Gracia **Phone:** 646956074 **mail:** ebueno@unizar.es

**Center:** Faculty of Health Sciences of the University of Zaragoza

**1. Introduction:**

We are writing to you to request your participation in a research project we are conducting at HCU-Lozano Blesa. Your participation is absolutely voluntary, in no case should you feel obliged to participate, but it is important to obtain the knowledge we need. This project has been approved by the Ethics Committee. Before making a decision, it is necessary that you:

- Read this entire document
- Understand the information contained in the document
- Ask as many questions as you feel necessary
- Make a thoughtful decision
- Sign the informed consent form if you wish to participate.

If you decide to participate, you will be given a copy of this sheet and the signed consent form. Please keep it in case you need it in the future.

**2. Why are you being asked to participate?**

You collaboration is requested because you suffer from carpal tunnel syndrome, and we want to study the immediate effect of a treatment technique on this pathology.

A total of 10 participants with these characteristics will participate in the study.

**3. What is the purpose of this study?**

The aim of this study is to see if a treatment technique is effective in people diagnosed with carpal tunnel syndrome. We want to study whether it has an immediate effect on the nerve that is affected in carpal tunnel syndrome (which is the median nerve).

**4. What do I have to do if I decide to participate?**

The principal investigator will have a short interview with you to collect data such as your age, sex, height, weight and dominant side.
Then, after the neurophysiologist physician has measured the nerve variables of interest, a brief treatment technique will be performed in the same facilities of the hospital's clinical neurophysiology service. After that, the initial

measurement will be repeated to see if there are changes or not. It will therefore be a single intervention that will not involve more than 15-20 extra minutes in the consultation room.
This study is expected to last until approximately May 2024.
In this study the participants will be divided into two groups: control and intervention. In the intervention group we will apply the technique of which we want to see the immediate effect, while in the control group no technique will be applied. The decision as to which group you belong to is not made by your doctor, but is decided randomly, with a 50% chance of being in each group. This is the inly way to be able to assess the real usefulness of the intervention.
This study is also masked, that is to say, neither you nor the doctor treating you will know which group you are assigned to.

**5. What risk or discomforts are involved?**

There are no risks or adverse effects described and is not painful either.

**6. Will I get any benefit for my participation?**

As this is a research study oriented to generate knowledge, you will not obtain any benefit for your participation, although you will contribute to scientific progress and social benefit.
You will not receive any financial compensation for your participation.

**7. How will my personal data be treated?**

Basic information about data protection
Data controller: Elena Bueno and Lucía Burgos.
Purpose: your personal data will be processed exclusively for the research work referred to in this document.
Legitimation: the processing of data for this study is legitimated by your consent to participate.
Recipients: no data will be transferred to third parties unless legally obliged to do so.
Rights: you may exercise your rights of access, rectification, deletion and portability of your data, limitation and opposition to its processing, in accordance with the provisions of the LO 3/2018 on the Protection of Personal Data and guarantee of digital rights and the General Data Protection Regulation (RGPD 2016/679) before the data protection officer of the institution, by sending an email to the address ebueno@unizar.es

Likewise, in compliance with the provisions of the RGPD, you are informed that, if you so wish you can go to the Data Protection Agency (https://www.aepd.es) to file a complaint when you consider that your rights have not been properly addressed.

The processing of your personal data will be carried out using techniques to maintain your anonymity through the use of random codes, so that your personal identity is completely hidden during the research process.

Based on the results of the research work, scientific communications may be prepared for presentation at congresses or scientific journals, but they will always be done with grouped data and nothing that could identify you will ever be disclosed.

**9. Who is financing the study?**

No specific funding is available for this study.

**10. Will I be informed of the results of the study?**

You have the right to know the result of this study, both the general results and those derived from your specific data. You also have the right not to know the results of the study if you wish to do so. For this reason we will ask you in the informed consent document which option you prefer. If you do wish to know the results, the investigator will send you the results.
If the results of the study are favorable, in case you belonged to the control group, you will be offered to receive the same intervention as the other group.

**11. Can I change my mind?**

Your participation is completely voluntary, you can decide not to participate or to withdraw from the study at any time without having to give explanations and without any repercussions on your health care. You only need to express your intention to the principal investigator of the study. If you decide to withdraw form the study, you may request the destruction of data, samples or other information collected about you.

**12. What happens if I have any questions during my participation?**

On the first page of this document, you will find the name and contact telephone number of the investigator responsible for the study. You can contact him/her in case you have any questions about your participation.

Thank you very much for your attention. If you finally wish to participate, please sing the attached consent form and we reiterate our gratitude for your contribution to the generation of scientific knowledge.

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**PROJECT TITLE:** Immediate effect of median nerve mobilization on neural conduction in patients with carpal tunnel syndrome. Randomized clinical trial.

I, ..... (participant's name and surname)

I have read the information sheet given to me.

I have been able to ask questions about the study and have received sufficient information about the study.

I have spoken to: .....(name of investigator)

I understand that my participation is voluntary.

I understand that I can withdraw from the study:

1) whenever I want
2) without having to explain myself
3) without affecting my health care.

I freely give my consent to participate in this study and I consent to the access and use of my data as stipulated in the information sheet given to me.

I wish to be informed about the results of the study: yes no (check all that apply)

I have received a signed copy of this Informed Consent.

Participant's signature: .....

Date: .....

I have explained the nature and purpose of the study to the named patient.

Signature of Investigator: .....

Date: