University of Barcelona - EUSES

Efficacy of Night Splinting and Neurodynamics on Cubital Tunnel Syndrome in Musicians: Randomized Controlled Trial

FINAL PROJECT

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Barcelona, 10th of May 2019

INDEX

ABSTRACT

BACKGROUND: The physical stress suffered make musicians prone to develop neuromuscular injuries. Around 9% of these injuries correspond to the Cubital Tunnel Syndrome, a peripheral ulnar nerve entrapment, due to the compression, traction and friction applied.

OBJECTIVE: To evaluate the effectiveness of night splinting and neurodynamics versus a conservative treatment (passive mobilisation with unspecific massage and cessation of the professional activity), concerning a rehabilitation time of 3 months.

METHODS: A total of 32 patients with Cubital Tunnel Syndrome will participate in this study. The inclusion criteria selected are: adults' professional musicians with a grade 3 entrapment neuropathy according to McGowan scale. The ratio of participants is 1:1 and the assignment blocks will be generated by a computer algorithm. The disability of the arm will be assessed by the Disability of the Arm, Shoulder and Hand (DASH) questionnaire, a 30-item scale focusing on the patient's health status. The specific treatment, applied to the experimental group, consists of a combination of a passive night splinting and neurodynamic mobilization during 3 months. The general treatment, applied to the control group, is based on a general program of passive mobilisation with unspecific massage, alongside cessation of their professional training and daily activity.

DISCUSSION: Traditional conservative programs have no evidence, whereas invasive programs are usually linked to associated adverse events and larger recovery periods. By means of the suggested experimental treatment, we expect to have better functional outcomes, less adverse events, and quicker recovery periods.

Keywords: *Cubital Tunnel Syndrome; DASH; Disability; Musicians; Rehabilitation.*

INTRODUCTION

Musicians, as artistic athletes, improve their motor skills until performing repetitive, fast and millimetrical movements during a very brief period of time. Repertoires usually become more challenging and increasingly difficult by the time: this fact will lead to the need of practicing even more and doing the same repetitive movements. Thus, performing music at an elite level requires greatly developed and integrated sensorimotor and neuromuscular body systems.[1] The physical stress that the musicians suffer, make them prone to frequently developing and suffering neuromuscular injuries over longer durations.[2] The majority of their injuries are caused by an imbalance between load and load-bearing capacity, overuse or misuse.[3] Studies have found that 50 to 80% of musicians can experience physical problems during their professional life.[4] Some of them will stop playing their instrument due to the aforementioned complaints.[5]

One of the most common injuries on musicians corresponds to nerve entrapment syndromes. According to different articles, the most frequent peripheral nerve entrapment neuropathies in the upper limb related to musicians is the Carpal Tunnel Syndrome, followed by Cubital Tunnel Syndrome (CTS, hereinafter) and Thoracic Outlet Syndrome.[3,6-9] Entrapment of the nerve means that there is a compression at a specific and predictable location where the nerve may be subjected to pressure between body tissues. Also it can occur from a source outside the body, when the nerve lies very superficially.[10]

Cubital Tunnel Syndrome (CTS) is a symptomatic ulnar nerve dysfunction at the level of the elbow resulting from a combination of compression, traction and friction.[11] The incidence of the CTS represents up to 9% of all musicians' injuries.[3] In addition, keyboardists and strings players are the most affected.[10]

The ulnar nerve may be compressed around the elbow on the following structures: the arcade of Struthers, the cubital tunnel (the most common), deep flexor aponeurosis medial intermuscular septum and medial epicondyle.[6,11]

The ulnar nerve passes through the cubital tunnel to enter the forearm between the two heads of the flexor carpi ulnaris muscle. It runs inside a gap of 4 mm in the cubital tunnel retinaculum, between the medial epicondyle and the olecranon, and its floor is the capsule and the posterior band of the medial collateral ligament of the elbow. The nerve stretches (5 mm) and slides through the cubital tunnel whenever there is an elbow movement.[6] While there is more than 90º of elbow flexion (alongside extension and shoulder abduction) the intraneural pressure increases by six times, and the tunnel shape changes from an oval to an ellipse and narrows the canal by 55%.[6,9]

For the patient, it may represent discomfort and disability, leading to a loss of function in the hand in extreme cases.[6] The main symptoms that a musician can perceive are: a positive Tinel phenomenon (tingling sensation) when typing around the cubital tunnel,[3] joint contractures, loss of coordination, pain along the ulnar nerve from the posteromedial elbow into the ulnar forearm or hand, paresthesia in the little finger and, in advanced phases, permanent loss of sensation and muscle weakness.[9,11]

Electrodiagnosis studies search information of the conduction velocity during the nerve interval around the elbow.[9] This can lead to a false-negative data resulting from variable compression of ulnar nerve fascicles and near normal conduction of unaffected large nerve fibbers during the test.[12] For a higher accuracy in the diagnosis, the McGowan classification of the CTS might be used. This classification, according to McGowan,[13] sorts the patients in three different grades [See Annex 1]:

- Grade I: sensory neuropathy only.
- Grade II: sensory and motor neuropathy, without muscle atrophy.
- Grade III: sensory and motor neuropathy with muscle atrophy.

In case of achieving a McGowan grade III, a musician either undergoes a surgical treatment (with the corresponding risks and the associated time of immobilization, inflammation, healing process and rebuilding of the elbow tissues) or follows a non-specific conservative treatment.

A non-specific and a specific treatment plan will be defined hereinafter, in line with the ‘Methods’ section.

On the one hand, the specific treatment plan is going to be applied to the experimental group. The new rehabilitation technique applied will have the duration of 3-month rehabilitation plan.[14] It consists about a combination of a passive night splinting and neurodynamic mobilization.

By the other hand, concerning the control group: patients will undergo a general program of passive mobilisation with unspecific massage, alongside cessation of their professional training and daily activity, as defined by Page et al.[15] Although it is one of the common treatments for CTS in Physical Therapy, there is limited evidence concerning the effectiveness of these interventions.[15]

Improving the knowledge has the importance to optimize the treatment applied to the patients: there is room for improvement in evidence-based treatments in Physical Therapy. Concerning the specific topic of the present article, several studies support and endorse the use of conservative treatments in Grades I and II according to McGowan. However, the Physical Therapy-based approaches on Grade III injuries are still scarce, since no evidence is available on conservative programs. Improvement is nonetheless stated following surgical intervention: Boone et al. propound submuscular and subcutaneous transposition of the nerves, simple decompression and/or medial epicondylectomy.[11] Following an invasive treatment, the healing process is usually long:[16] therefore, musicians are not allowed to mobilize the elbow during some days leading, thus, to a loss of skills and training sessions.

The gap of knowledge for this particular condition relays, therefore, on the lack of scientific evidence on conservative treatments concerning Grade III subjects. Building a strong protocol and pattern of conservative treatment for the aforementioned patients would enhance the recovery time, quality of life and functionality of musicians affected by Grade III CTS.

HYPOTHESIS

In this study it is hypothesized that

- The experimental treatment enhances the functionality of the upper limb compared with the conventional conservative treatment.
- The application of an alternative to the conservative and common treatment plan could help to reduce the time of recovery and return-to-play, for musicians, during the rehabilitation weeks.

From a statistical perspective, the **null hypotheses** will be defined as follows: (i) “The experimental treatment shows no difference in terms of functionality of the upper limb compared with the conventional conservative treatment” (ii) “The application of an alternative to the conservative and common treatment plan shows no difference in the reduction of the time of recovery and return-to-play, for musicians, during the rehabilitation weeks”, whereas the **alternative hypotheses** would be defined as follows: (i) “The experimental treatment shows better outcomes in terms of functionality of the upper limb compared to the conventional conservative treatment” (ii) “The application of an alternative to the conservative and common treatment plan shows higher reduction of the time of recovery and return-to-play, for musicians, during the rehabilitation weeks”

OBJECTIVES

The different purposes of this study are:

- To evaluate the effectiveness of the experimental treatment versus the conservative treatment concerning the functional recovery process during a period of time of 3 months.
- To determine the effects of the experimental treatment (neurodynamics, night splinting) in grade III on CTS on McGowan scale.
- To fill the gap of a conservative treatment concerning the grade III.

MATERIAL AND METHODS

1- **Study Design**

This study is a Randomized Controlled Trial Study with two different groups of treatment.

2- **Study Setting**

The study will be conducted in the institution: “Institut de Fisiologia i Medicina de l’Art” (Carretera de Montcada, 668, Terrassa, Barcelona).

3- **Participants - Inclusion & Exclusion Criteria**

- Inclusion criteria:
    - Professional musicians (average training above 20 hours per week prior to the injury) with a professional experience of, at least, 5 years.[17]
    - 18 year old and above.
    - Diagnosed grade III Carpal Tunnel Syndrome according to the McGowan scale[13] [See Annex 1].
- Exclusion criteria:[14]
    - Ulnar nerve hypermobility.
    - Symptomatology in medial and/or radial nerve.
    - Other additional neuropathies.
    - Carpal Tunnel Syndrome secondary to elbow deformity.
    - Palpable swelling or subluxations.
    - Congenital anomalies.
    - Prior trauma.
    - Cervical radiculopathy.
    - Grades I or II on the McGowan scale.
    - Arthritis.
    - Diabetes.

4- **Sampling type and Sample Size**

Nonprobabilistic convenience sampling will be used. Participants will be therefore consecutively selected, according to their accessibility. The sampling process will finish whenever the total amount of participants needed, will be achieved.[18]

As for the sample size, no consensus is observed when assessing sample sizes from similar studies (7 subjects in Oskay et al., 19 subjects in Shah et al., 44 subjects in Biggs and Curtis et al., 70 subjects in Gervasio et al., 85 subects in Chan et al. and 152 subjects in Bartels et al.) with sizes ranging from 7 to 152 subjects.[2,14,19-22] Thus, the sample size has been calculated according to the online resource ClinCalc.com (ClinCalc LLC, Indianapolis, Indiana)[23] predefining the following parameters: alpha (α) = 5%, Confidence Interval (CI) = 95%, Statistical Power = 80%, enrolment ratio = 1, Minimal Clinically Important Change Score = 10% (predefining an a-priori change in the main outcome of 10%, as defined by Gummesson et al.[24] The results reveal a sample size of 32 patients, amongst which 16 will be assigned to the intervention group, whereas the extant 16 will correspond to the control group.

5- **Recruitment**

Participants will be recruited amongst professional musicians from the “Institut de Fisiologia i Medicina de l’Art” in Terrassa, through medical triage, from September to November 2019. Moreover, different posters and notices, in order to support and enhance the participants willingness to take part in the study, as stated by Patel et al.[25] These support measures can be posted in the “Escola Superior de Música de Catalunya” (ESMUC), “Conservatori Superior de Música del Liceu” and some orchestras of the region.

6- **Randomization and Assignment**

Since the defined enrolment ratio is 1:1, the block randomization method will be used. As defined by Suresh et al.[26] the block randomization is a suitable method to randomize participants into groups resulting in equal sample sizes.

As suggested by Efird et al.[27] the assignment blocks will be generated by computer algorithm written in SAS© (Cary, NC).

7- **Selection and Definition of Variables**

The independent variable corresponds to the treatment group, with two different levels (experimental VS conservative treatment), whilst the dependent variable corresponds to the disability of the arm (measured through the DASH questionnaire).

8- **Measurement of the Variables / Outcomes**

The outcome variable is the disability of the arm. The instrument selected to assess the aforementioned variable will be the Disability of the Arm, Shoulder and Hand (DASH) questionnaire: this instrument is an upper-extremity specific outcome measure with the aim of facilitating comparisons among different upper-extremity conditions in terms of health burden.[28] The scale provides changes over time for groups or individuals and the scores lead to the comparison of different groups.

The DASH is a 30-item scale focusing on the patient's health status. The items ask about the degree of difficulty in performing different physical activities because of an arm, shoulder or hand problem (21 items), the severity of each of the symptoms or pain, activity-related pain, tingling, weakness and stiffness (5 items), as well as the problem's impact on social activities, work, sleep and self-image (4 items). Each item has five possible response options. The score ranges from 0 (no disability) to 100 (most severe disability).[29] A 10-point difference in mean DASH score might be considered as a minimal important change.[24] The DASH instrument measures disability; lower levels of disability will entail better levels of functioning and, conversely, high scores in the DASH scale will correspond to lower levels of functioning.[30] [See Annex 2]

Measures from both groups will be collected at baseline, 3 months (end of treatment) and a follow-up assessment after 1 year.[14] So, DASH questionnaire will be used to know which of the two interventions applied are more useful, by comparing the scores between both groups.

9- **Intervention**

The intervention will be based in a 3-month rehabilitation plan[14] combining night splinting and neurodynamic mobilization compared to a conservative treatment consisting of non-specific passive mobilisation and massotherapy.

The experimental treatment consists of:

- Night Splinting: patients will be treated with a rigid night-time orthosis holding the elbow at 45º of flexion for a total length of 3 months. In order to standardize the splinting, the orthosis will be a rigid splinting by Hely & Weber (Santa Paula, CA).[14]

  Patients will be requested to fill out and sign a register of having worn the orthosis over-night [See Annex 3].
- Neurodynamics Mobilization: the main aim of these techniques is to reduce fibrosis, therefore increasing the vascular and axoplasmic flow, and restoring, thus, the tissue mobility. One movement loads the peripheral nervous system while the other movement unloads it.[19] The passive mobilization consists in gliding the nerve without tensioning it. The technique performed by the physiotherapist, 3 times a week during the 3-month treatment period, will respect the pain and tension barriers within the range of motion. As stated by Oskay et al.[19] the treatment shall be applied in three different positions.
  1. Patient in supine position, shoulder in depression, 90º of abduction and external rotation. The neck placed in a contralateral bending position and the elbow at 90º of flexion. A passive pronation of the forearm is performed by the physiotherapist.
  2. In addition to the position defined in [1], the physical therapist places the forearm in pronation and performs a passive elbow flexion from 90º to 140º.
  3. Starting from the final position achieved in [2], with the elbow in 90º of flexion, the physical therapist performed shoulder depression from 90º to 120º of abduction. Extension of the wrist may also be applied.

The aforementioned positions will be applied to the patients 5 times in every session (3 times a week during a 3-month period).

As for the control group the treatment plan will consist on: patients will undergo a general program of passive mobilisation (10 minutes) of the elbow with unspecific massage (20 minutes), alongside cessation of their professional training and activity, as defined by Page et al:[15] although it is one of the common treatments for CTS in Physical Therapy, there is limited evidence concerning the effectiveness of these interventions.[15] This treatment will be applied during 30 minutes simultaneously with the experimental group rehabilitation.

10- **Blinding / Masking**

Single blind trial: the investigator assessing the patients at baseline, 3 months and 1 year will be blinded and independent from the therapists treating both groups.

11- **Statistical Analysis**

Repeated measures ANOVA will be used. Since this particular test requires one independent categorical variable (treatments) and one continuous dependent variable (mean scores in the DASH test) across three different time points. The alpha level will be set at 5%, whereas the Confidence Interval will be set at 95%. All analyses will be performed with SPSS 25.0 (Armonk, NY).

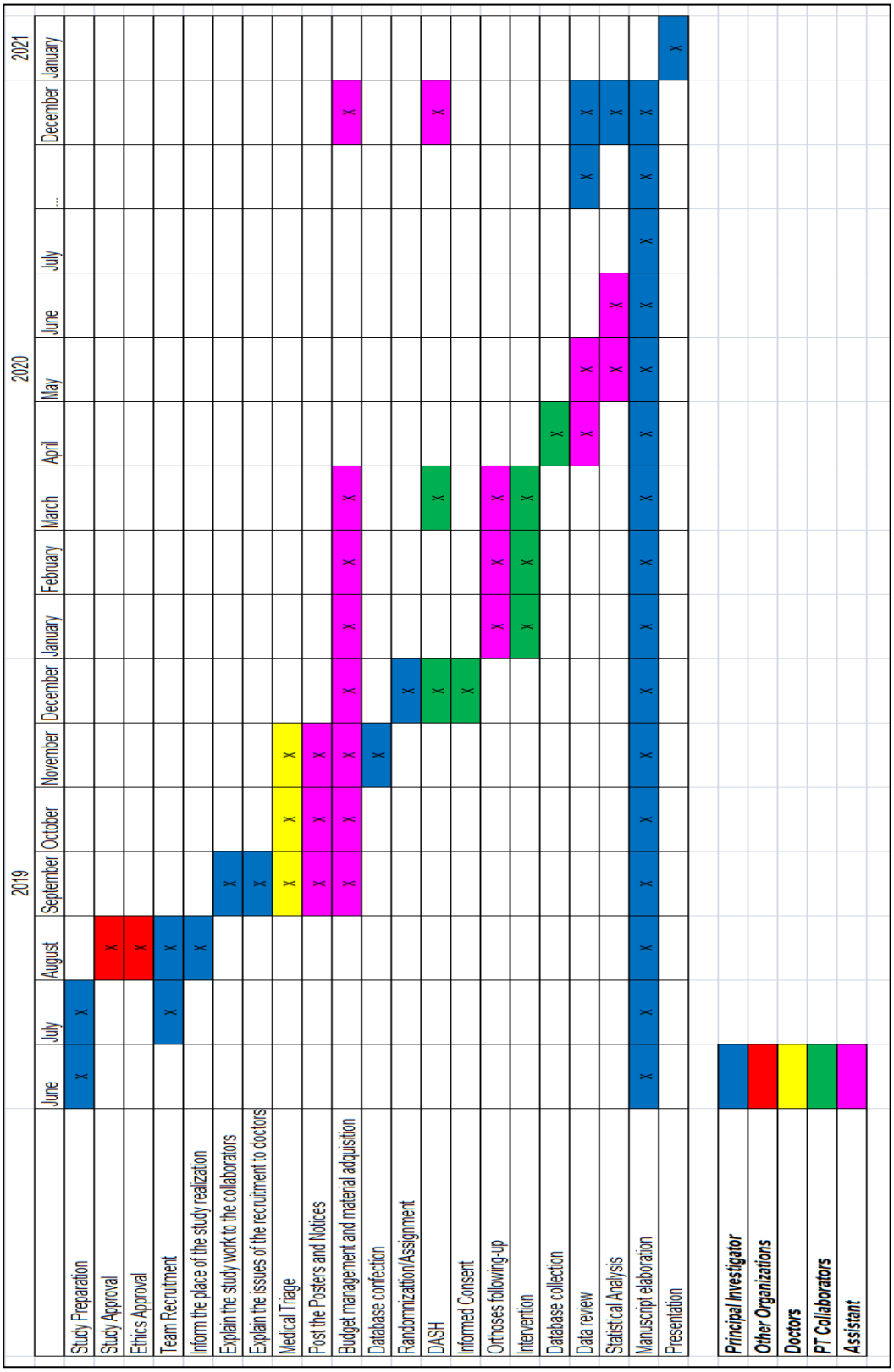
ETHICAL ASPECTS

The present study will be designed to adhere to the tenets of the Declaration of Helsinki, and will be submitted to the research ethics committee and corresponding institutional review board from the University of Barcelona.

Informed Consent will be also collected from all the participants in the study [See Annex 4].

The corresponding financial or other competing interests from the investigators involved in the study will also be provided.

CALENDAR / PLANNING



Source: Own elaboration

ROLE OF THE INVESTIGATORS

Some investigators will be needed to carry out this study:

- The coordination and direction of the study will be carried out by Ms. Maria Júdez Torres, in quality of **principal investigator** from the Rehabilitation Research Group from EUSES. Her main tasks will consist of:
    - Choosing and giving the basic formation to the research collaborators;
    - Study implementation;
    - Management of the economic resources;
    - Responsibility of the therapeutic approach on the control and experimental groups;
    - Analyzing results;
    - Promotion an diffusion of the results and findings of the present study.

- A total of 12 **assistant researchers** overall:
    - 3 doctors of the “Institut de Fisiologia i Medicina de l’Art” will perform the recruitment of the study;
    - For 32 patients, 8 physiotherapists will be required, to perform the rehabilitation plan: 4 of them will be responsible for the control group whereas the extant 4 will work with the experimental group.

      Every physical therapist will entrust with 4 subjects every afternoon of session during 3 months.

      All physical therapists involved in the present project will be conveniently trained and briefed to apply the different techniques homogeneously, with the aim of enhancing the inter-applier reliability.
    - An assistant will be responsible for logistical tasks: scheduling of patients sessions, programming a reminder at 21h00 to patients in order to use the orthosis, and also controlling the register of use of the aforementioned orthosis [See Annex 3].

BUDGET

This investigation will require instruments and materials to adequately perform the treatment proposed. The resources will be divided in fungible and non fungible groups:

Fungible	Non Fungible
• Hand soap • Hygienic paper • Latex Gloves • Massage cream • Paper • Pencils • Pen	• Beds • Chairs • Laptop • Printer • 16 Orthosis: rigid splinting by Hely & Weber (Santa Paula, CA) (14) • Table • Towels

Source: Own elaboration

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ANNEXES

Annex 1 - McGOWAN SCALE

Grades	Symptoms and Signs
I	Sensory neuropathy only
II	Sensory and motor neuropathy, without muscle atrophy
III	Sensory and motor neuropathy; muscle atrophy present

Source: Own elaboration. Based on McGowan (13)

Annex 2 - The DASH Questionnaire

	No	Mild	Moderate	Severe	Unable
1. Opening a tight or a new jar	1	2	3	4	5
2. Writing	1	2	3	4	5
3. Turning a key	1	2	3	4	5
4. Preparing a meal	1	2	3	4	5
5. Pushing open a heavy door	1	2	3	4	5
6. Placing an object on shelf above the head	1	2	3	4	5
7. Doing heavy household chores	1	2	3	4	5
8. Gardening or doing yard work	1	2	3	4	5
9. Making a bed	1	2	3	4	5
10. Carrying a shopping bag or briefcase	1	2	3	4	5
11. Carrying a heavy object (< 5 kg)	1	2	3	4	5
12. Changing a light bulb overhead	1	2	3	4	5
13. Washing or blowing dry the hair	1	2	3	4	5
14. Washing the back	1	2	3	4	5
15. Putting on a pullover sweater	1	2	3	4	5
16. Using a knife to cut food	1	2	3	4	5
17. Recreational activities that require little effort	1	2	3	4	5
18. Recreational activities that require taking some force or impact through the arm, shoulder or hand	1	2	3	4	5
19. Recreational activities that require moving the arm freely	1	2	3	4	5
20. Managing transportation needs (getting from one place to another)	1	2	3	4	5
21. Sexual activities	1	2	3	4	5
22. Social activities	1	2	3	4	5
23. Work and other daily activities	1	2	3	4	5
24. Pain	1	2	3	4	5
25. Pain when performing activities	1	2	3	4	5
26. Tingling	1	2	3	4	5
27. Weakness	1	2	3	4	5
28. Stiffness	1	2	3	4	5
29. Difficulty in sleeping	1	2	3	4	5
30. Impact on self-image	1	2	3	4	5

Source: Own elaboration. Based on Athrosy (28)

Annex 3 – Orthosis: Register of Use Form

DAY 1	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
Hours: **Sign:**	**Hours:** **Sign:**	**Hours:** **Sign:**	**Hours:** **Sign:**	**Hours:** **Sign:**	**Hours:** **Sign:**	**Hours:** **Sign:**
DAY 8	**DAY 9**	**DAY 10**	**DAY 11**	**DAY 12**	**DAY 13**	**DAY 14**
Hours: **Sign:**	**Hours:** **Sign:**	**Hours:** **Sign:**	**Hours:** **Sign:**	**Hours:** **Sign:**	**Hours:** **Sign:**	**Hours:** **Sign:**
DAY 15	**DAY 16**	**DAY 17**	**DAY 18**	**DAY 19**	**DAY 20**	**DAY 21**
Hours: **Sign:**	**Hours:** **Sign:**	**Hours:** **Sign:**	**Hours:** **Sign:**	**Hours:** **Sign:**	**Hours:** **Sign:**	**Hours:** **Sign:**
DAY 2-2	**DAY 23**	**DAY 24**	**DAY 25**	**DAY 26**	**DAY 27**	**DAY 28**
Hours: **Sign:**	**Hours:** **Sign:**	**Hours:** **Sign:**	**Hours:** **Sign:**	**Hours:** **Sign:**	**Hours:** **Sign:**	**Hours:** **Sign:**
DAY 29	**DAY 30**	**DAY 31**	**DAY 32**	**DAY 33**	**DAY 34**	**DAY 35**
Hours: **Sign:**	**Hours:** **Sign:**	**Hours:** **Sign:**	**Hours:** **Sign:**	**Hours:** **Sign:**	**Hours:** **Sign:**	**Hours:** **Sign:**
DAY 36	**DAY 37**	**DAY 38**	**DAY 39**	**DAY 40**	**DAY 41**	**DAY 42**
Hours: **Sign:**	**Hours:** **Sign:**	**Hours:** **Sign:**	**Hours:** **Sign:**	**Hours:** **Sign:**	**Hours:** **Sign:**	**Hours:** **Sign:**
DAY 43	**DAY 44**	**DAY 45**	**DAY 46**	**DAY 47**	**DAY 48**	**DAY 49**
Hours: **Sign:**	**Hours:** **Sign:**	**Hours:** **Sign:**	**Hours:** **Sign:**	**Hours:** **Sign:**	**Hours:** **Sign:**	**Hours:** **Sign:**
DAY 50	**DAY 51**	**DAY 52**	**DAY 53**	**DAY 54**	**DAY 55**	**DAY 56**
Hours: **Sign:**	**Hours:** **Sign:**	**Hours:** **Sign:**	**Hours:** **Sign:**	**Hours:** **Sign:**	**Hours:** **Sign:**	**Hours:** **Sign:**
DAY 57	**DAY 58**	**DAY 59**	**DAY 60**	**DAY 61**	**DAY 62**	**DAY 63**
Hours: **Sign:**	**Hours:** **Sign:**	**Hours:** **Sign:**	**Hours:** **Sign:**	**Hours:** **Sign:**	**Hours:** **Sign:**	**Hours:** **Sign:**

DAY 64	DAY 65	DAY 66	DAY 67	DAY 68	DAY 69	DAY 70
Hours: **Sign:**	**Hours:** **Sign:**	**Hours:** **Sign:**	**Hours:** **Sign:**	**Hours:** **Sign:**	**Hours:** **Sign:**	**Hours:** **Sign:**
DAY 71	**DAY 72**	**DAY 73**	**DAY 74**	**DAY 75**	**DAY 76**	**DAY 77**
Hours: **Sign:**	**Hours:** **Sign:**	**Hours:** **Sign:**	**Hours:** **Sign:**	**Hours:** **Sign:**	**Hours:** **Sign:**	**Hours:** **Sign:**
DAY 78	**DAY 79**	**DAY 80**	**DAY 81**	**DAY 82**	**DAY 83**	**DAY 84**
Hours: **Sign:**	**Hours:** **Sign:**	**Hours:** **Sign:**	**Hours:** **Sign:**	**Hours:** **Sign:**	**Hours:** **Sign:**	**Hours:** **Sign:**
DAY 85	**DAY 86**	**DAY 87**	**DAY 88**	**DAY 89**	**DAY 90**	
Hours: **Sign:**	**Hours:** **Sign:**	**Hours:** **Sign:**	**Hours:** **Sign:**	**Hours:** **Sign:**	**Hours:** **Sign:**	

***Hours:** number of hours that the patient has worn the orthosis overnight.

Source: Own elaboration.

Annex 4 - INFORMED CONSENT

INFORMED CONSENT FORM

Informed Consent form for the study **'Efficacy of Night Splinting and Neurodynamics on Cubital Tunnel Syndrome in Musicians: Randomized Controlled Trial'**

Principal Investigator: Maria Júdez Torres

Organization: EUSES Physiotherapy Barcelona

This Informed Consent Form has two parts:

- Information Sheet (to share information about the research with you)
- Certificate of Consent (for signatures if you agree to take part)

You will be given a copy of the full Informed Consent Form

PART I: Information Sheet

Introduction

I am Maria Júdez, working on the project 'Efficacy of Night Splinting and Neurodynamics on Cubital Tunnel Syndrome in Musicians: Randomized Controlled Trial' I am going to give you information and invite you to be part of this research. You do not have to decide today whether or not you will participate in the research. Before you decide, you can talk to anyone you feel comfortable with about the research.

There may be some words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain. If you have questions later, you can ask them to me.

Purpose of the research

The physical stress suffered make musicians prone to develop neuromuscular injuries. Around 9% of these injuries correspond to the Cubital Tunnel Syndrome, a peripheral ulnar nerve entrapment, due to the compression, traction and friction applied. The objective of the present study is to evaluate the effectiveness of night splinting and neurodynamics versus a conservative treatment (passive mobilisation with unspecific massage and cessation of the professional activity), concerning a rehabilitation time of 3 months.

Type of Research Intervention

This research will involve a Physical Therapy treatment during three months.

Participant selection

We are inviting all adults with Cubital Tunnel Syndrome attending the present institution.

Voluntary Participation

Your participation in this research is entirely voluntary. It is your choice whether to participate or not. Whether you choose to participate or not, all the services you receive at this clinic will continue and nothing will change.

Procedures and Protocol

Since we do not know if a new protocol for treating Cubital Tunnel Syndrome is better than the currently available treatment, we need to compare the two of them. To do this, we will put people taking part in this research into two groups. The groups are selected by chance, as if by tossing a coin.

Participants in one group will be provided with the test while participants in the other group will be provided with the classical treatment. This information will be in our files, but we will not look at these files until after the research is finished. We will then compare which of the two has the best results.

Side Effects

No unwanted effects are expected.

Confidentiality

The information that we collect from this research project will be kept confidential. Information about you that will be collected during the research will be put away and no-one but the researchers will be able to see it. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is.

Sharing the Results

The knowledge that we get from doing this research will be shared with you through community meetings before it is made widely available to the public. Confidential information will not be shared. There will be small meetings in the community and these will be announced. After these meetings, we will publish the results in order that other interested people may learn from our research.

Right to Refuse or Withdraw

You do not have to take part in this research if you do not wish to do so. You may also stop participating in the research at any time you choose. It is your choice and all of your rights will still be respected.

Who to Contact

If you have any questions you may ask them now or later, even after the study has started. If you wish to ask questions later, you may contact Maria Júdez Torres (maria.judez97@gmail.com)

PART II: Certificate of Consent

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

Print Name of Participant _____

Signature of Participant _____

Date _____

Day/month/year

If illiterate

A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumb-print as well.

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness_____ **AND** **Thumb print of participant**

Signature of witness _____

Date _____

Day/month/year

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the following will be done:

Apply two different treatments to subjects with Cubital Tunnel Syndrome;

Collect data on different clinical outcomes;

Compare the results of both groups, to evaluate the comparative efficacy of both treatments.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this ICF has been provided to the participant.

Name of Researcher MARIA JÚDEZ TORRES

Signature of Researcher _____

Date _____

Day/month/year

Source: WHO template of Informed Consent for Clinical Studies. Available on-line: *https://www.who.int/rpc/research_ethics/informed_consent/en/*