MODEL PROTOCOL FOR SUBMITTING PROJECTS TO THE CEIm OF

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RESEARCH PROJECT TO BE EVALUATED BY THE CLINICAL RESEARCH ETHICS COMMITTEE

Title and details

PROJECT NAME: Effectiveness of a combined therapy of the Super Inductive System (SIS) with a therapeutic exercise program of physiotherapy and health education in lateral tendinopathies of the elbow.

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Structured summary of the project

Background: Lateral epicondyalgia is the most common cause of lateral elbow pain, affecting between 1% and 3% of the population. It affects strength, functionality and quality of life and causes limitations in work and activities of daily living. Therefore, it constitutes a major public health problem.

Scientific evidence suggests the application of conservative physiotherapeutic treatment, as the first line of action; although there is heterogeneity and treatment guidelines are not clear.

Rest and drug administration provide short-term pain relief. They are usually the first therapeutic step, although it does not solve the problem and can promote relapses.

Kinesitherapy can improve pain, strength, and functionality. Evidence advises it as a first-line conservative treatment. Its cost-benefit ratio is very favorable. The application of thermotherapy and electrotherapy reduce pain and improve functionality compared to placebo.

This study aims to assess the efficacy of the Super Inductive System (SIS), combined with a conventional kinesitherapy protocol.

Hypothesis: The combined therapy of the SIS, with a therapeutic exercise program of upper limb physiotherapy and health education, will promote the reduction of pain, improve the mobility and functionality of the affected limb, increase grip strength, facilitate the return to activities of daily living (ADL), as well as the perception of improved quality of life in people with lateral elbow tendinopathies.

Objective: To evaluate the effectiveness of SIS combined with a therapeutic exercise program of physiotherapy and health education in cases of lateral tendinopathy of the elbow in people aged 18 years or older, compared to the application of SIS with a non-therapeutic dose and the performance of conventional therapeutic exercise and health education treatment.

Methodology: Interventional, experimental, prospective study. Randomized Clinical Trial, with triple blind of the principal investigator, the evaluator and the user. With control group (SIS with non-therapeutic dose, therapeutic exercise and health education) and intervention group (SIS with therapeutic dose, therapeutic exercise and health education). The study will be multicenter, with a quantitative methodology, carried out in three Rehabilitation and Physiotherapy Services (Mataró, Sant Andreu (Barcelona) and Drassanes (Barcelona)). The three centres are in the field of Primary Care, of the Catalan Institute of Health (ICS).

Data collection will be carried out before and after the intervention and controls 3 and 6 months after the end of the processing.

Variables of interest: pain (VAS/Algometry), mobility (goniometer), function (QuickDASH), strength (Dynamometry) and quality of life (EQ-5D-5L).

Intra- and intergroup inference tests will be carried out on the dependent variables. The data will be processed in accordance with current legislation.

The data will be managed through RedCAP (Research Electronic Data Capture).

The study will be recorded in the ClinicalTrials.gov.

Expected results: A statistically significant improvement is expected in the intervention group compared to the control group, to extrapolate the treatment to the general population with lateral elbow epicondylalgia. It is expected that the use of the SIS will lighten recovery time, reduce the number and time of temporary disabilities (TD) and pharmacological expenditure for cases of epicondylgia.

Applicability: SIS is an innovative and non-invasive therapeutic technology. It reduces acute and chronic pain, improves joint mobility and promotes muscle strengthening in cases of acute and chronic tendinopathies. Its implementation could accelerate the recovery of the pathology. The aim is to obtain evidence on its effectiveness and cost-efficiency, contributing to the reduction of the number of temporary work disabilities and their duration, treatment and recovery times, as well as expenditure on pharmacological treatment.

Relevance: The use of SIS can improve effectiveness and cost-efficiency, contributing to the reduction of the number of temporary work disabilities and their duration, treatment and recovery time, as well as expenditure on medicines in those patients affected by epicondylitis.

It will provide evidence to incorporate a new therapeutic tool into clinical practice, improving treatment efficacy, reducing costs and offering a better patient experience in primary care. The SIS will be key to developing a more sustainable and advanced healthcare, putting the company at the forefront of innovation in physiotherapy and rehabilitation.

Keywords

Lateral Epicondylitis, Super Inductive System, high-intensity electromagnetic stimulation, exercises, pain, functionality.

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LIST OF ABBREVIATIONS

AP: Primary Care.

ADL: Activities of Daily Life.

CAP: Primary Care Centre.

CEIC: Clinical Research Ethics Committee.

CI: Informed Consent.

eCAP: Coordination and Primary Care Team.

EVA: Visual Analogue Scale.

ENV: Visual Numerical Scale.

FIP: Patient Information Sheet.

GC: Control Group.

GI: Intervention Group.

GIS: Management and Services.

ICS : Catalan Institute of Health.

PI: Principal Investigator.

TD: Temporary Disabilities.

MF: Family Doctor.

SIS: *Super Inductive System*. Super Inductive System.

SPSS: *Statistical Package for the Social Sciences*.

TCAI: Nursing Assistant Care Technician.

Background and current status of the subject. Justification of the project

BACKGROUND AND CURRENT STATUS OF THE SUBJECT

Tendon diseases constitute a significant part of musculoskeletal disorders and represent a leading cause of disability worldwide. Unresolved (chronic) inflammatory states have been associated with the onset and progression of tendon disorders, contributing to undesirable immune stimulation and tissue damaging effects (1).

Epicondyalgia is a musculoskeletal disorder that causes pain and dysfunction in the upper extremity. It is considered to be the most common cause of elbow pain (2,3).

There is controversy regarding the terminology used to name lateral elbow pain. The most commonly used term is "lateral epicondylitis", followed by "tennis elbow" and "lateral epicondylgia". Although epicondylitis is the most commonly used, this alteration is not inflammatory but degenerative. It is a tendinopathy caused by degeneration of the tendon as a result of its excessive and repetitive use (4).

There is involvement of the extensor muscles that are inserted into the epicondyle. The most frequent involvement occurs at the level of the insertion of the extensor carpi radial brevis muscle, although it can also appear in the insertion of the extensor digitorum comum muscle and extensor ulnar carpital. Tendinopathy appears not only with the practice of racket sports but is also common in people who perform tasks with wrist extension, radial deviation, supination and repetitive grip, leading to limitations in daily work and activities of daily living (2,3).

Lateral epicondyalgia is the most common cause of lateral elbow pain. It often develops as an affectation related to the world of work, associated with demanding physical work, excessive use, recurrent movements of the upper limbs, weight training and repetitive vibrational movements. It is therefore a major public health problem (5,6).

It affects approximately 1 to 3 percent of the population (7). It seems to affect men and women in the same proportion, but there are studies that report a greater effect on women. The incidence is 5.5 cases per 1000 people per year, mostly affecting people between 40 and 59 years of age in their dominant arm (3).

The symptoms that occur with epicondyalgia are pain in the area of insertion of the epicondylar muscles, affecting strength, functionality and quality of life (8).

The main treatment objectives are focused on decreasing pain, preserving mobility, improving muscle strength and endurance as well as helping users improve functional capacity and quality of life (3).

To perform the examination and diagnose epicondylgia, various tests and questionnaires can be used. The clinical tests of Cozen and Mill can be used. The **Cozen maneuver** is a clinical test used to diagnose lateral epicondylitis. It is performed with the patient sitting, with the elbow arm at 90º of flexion, the forearm in pronation and the wrist in slight radial deviation. The patient must perform a

resisted extension of the wrist while the examiner applies pressure. It can also be done by asking him to "take a chair". If the patient experiences pain in the lateral area of the elbow, the test is considered positive (9). Mill**'s maneuver**, also used to diagnose lateral epicondylitis, involves putting the extensor muscles of the wrist under passive tension. The patient can be sitting or standing, with the elbow bent and the forearm in pronation. The examiner flexes the patient's wrist and stretches the elbow to the maximum. If the patient experiences pain in the epicondylar area, the test is considered positive. Mill's test has excellent reliability and Cozen's has good reliability (9). The diagnosis is mainly clinical, but sometimes it can be complemented with an ultrasound examination (9,10). To assess pain, the Visual Analogue Scale (VAS), the Visual Numerical Scale (ENV), the manual pressure algometer, among others, can be used (3,10). A dynamometer can be used to measure the isometric gripping force of the hand (11).

Scientific evidence suggests the application of conservative treatment for lateral elbow pain, as the first line of action. Clinical guidelines and the literature do not identify the most effective non-surgical treatment (12). Although heterogeneity exists and treatment guidelines are unclear, evidence suggests that physiotherapeutic rehabilitation appears to be effective in acute and chronic conditions (2).

There are different treatments used to address epicondylalia.

Rest and drug administration provide short-term pain relief. They are usually the first therapeutic step, although it does not solve the problem and can promote relapses (13).

One of the most common physiotherapy treatments in clinical practice for epicondylitis is the application of a therapeutic exercise program consisting of warm-up, static stretching exercises, and eccentric and isometric training exercises (3). Kinesitherapy, with the performance of eccentric exercise, can improve pain, strength and functionality. Evidence suggests it as a first-line conservative treatment. Its cost-benefit ratio is very favourable (13,14,15). A 2024 clinical trial concluded that proprioception exercises have limited added value in terms of pain, function, hand grip strength, and dexterity but may be beneficial for improving joint position (16). Eccentric exercise is considered as a first-line conservative treatment in the approach of lateral elbow tendinopathies for the improvement of pain and muscle strength (17).

In a study published in 2018, he talks about the importance of increasing tolerance to tendon load, including strength exercises, but also adding speed and energy storage and release. Although the study is specific to achilles and patellar tendinopathy, the information obtained could be extrapolated to elbow tendinopathy. The aim is to incorporate progressive loading into the tendon with isometric, strength, functional strength and speed exercises (18).

The application of thermotherapy and electrotherapy decreases pain and improves functionality compared to placebo (7). Greater benefits and improvement of symptoms can be found with the application of electrotherapy in combination with manual physiotherapy techniques and therapeutic exercise. Electromagnetic fields, TENS, laser, shortwave, iontophoresis or ultrasound are the most used in the

treatment of epicondylitis. Cryotherapy can be effective in reducing local pain at the end of treatment. Gel massage is effective as part of a multimodal approach to treat any type of tendon pathology (3). A 2021 systematic review and meta-analysis examined the outcomes of non-surgical treatments for lateral epicondylitis. Fifty-eight randomized controlled trials were included and concluded that patients who received electrotherapy and physiotherapy reported statistical and clinical improvements in pain and function compared to placebo (19). A 2022 meta-analysis included twenty-three clinical trials with 1363 participants to compare the efficacy of physiotherapy and electrophysiotherapy treatments for the treatment of lateral epicondylitis. They concluded that Pulsed Electromagnetic Fields (PEMF) therapy was associated with pain reduction and that acoustic wave and light therapy favoured an increase in grip strength (to grip objects firmly) (12). PEMF can be integrated into the application of effective therapies to treat inflammation in tendinopathic conditions (1).

The Super Inductive System (SIS) or high-intensity pulsed magnetic field has been shown to be effective in addressing tendinopathies, although there is very little evidence. In 2024, a study with 34 users was published, with which the effect of a single PEMF application on pain perception was investigated. The results showed an immediate decrease in pain, which persisted for at least a week (20).

Tendon disorders often cause decreased function and muscle atrophy. A 2024 study conducted with rats confirms that pulsed electromagnetic fields have demonstrated potential to improve tendon fiber structure and muscle recovery, accelerating physiological recovery (21).

It is important to include ergonomic and postural hygiene recommendations in the treatment. These indications could include avoiding repetitive wrist and elbow movements, not performing activities that can worsen pain, modifying the work environment to improve ergonomics, taking into account that exercises should not increase pain, among others (3).

Manual therapy facilitates the reduction of pain and improves joint mobility (13). The therapeutic exercise program can be combined with manual therapy techniques such as Cyriax, Mulligan manipulation, myofascial trigger point approach (manual therapy and dry needling), soft tissue mobilization, and mobilization and manipulation of the wrist and radial joints (3). In a 2023 systematic review, they conclude that manual therapy and eccentric strength training are the two physiotherapeutic treatment methods that have the greatest beneficial effects and that the cost-benefit ratio is more favourable (22).

Kinesiotaping or neuromuscular bandage is frequently used to address musculoskeletal pathology and offers positive effects on pain caused by wrist extension against resistance in epicondylitis (3). The effect, both immediate and short-term, with the placement of Kinesiotape is unclear (23).

The use of forearm orthosis can immediately reduce pain during contraction and improve pain-free grip strength, but not maximum grip strength (24). Its use is more indicated during the first phase of treatment or the onset of pain, when it is not possible to avoid the activity that generates or worsens the pain (3).

The application of extracorporeal shock waves has been shown to relieve pain and functional impairment (25). On the other hand, in a 2021 systematic review and meta-analysis, they present low to moderate evidence regarding the clinical benefits of extracorporeal shockwave therapy compared to sham interventions (26). Mechanical stimulation obtained by extracorporeal shock waves and pulsed electromagnetic fields may play a role in the treatment of tendinopathy and for tendon regeneration by increasing the expression of growth factors (27).

Some studies show low evidence on the use of dry needling to reduce pain, pain-related disability and short-term strength (28). Others show good therapeutic effects on pain intensity, function, and grip strength (29).

Infiltrations can put patients at greater risk of adverse effects compared to different conservative treatments (19); although biological treatments for the non-surgical approach to epicondylitis are increasingly used, such as platelet-rich plasma, autogenous blood injections and stem cell therapy (3).

Surgical treatment should be carried out as a last option, if conservative treatment has not improved the symptoms. Three types of surgical approach are used; open, percutaneous or arthroscopic. The latter is the one that obtains the best functional results (30).

This study aims to assess the efficacy of SIS, combined with a therapeutic exercise and health education protocol. There is very little evidence on the effectiveness of SIS although there are some publications of pilot studies or case studies; both in epicondyalgia (31) and in other conditions (32).

JUSTIFICATION OF THE PROJECT

The proposed study aims to evaluate the efficacy of SIS in lateral elbow tendinopathies. It is an injury frequently related to repetitive movements of the elbow and hand, during sports, work or domestic activities, which require intense force in inappropriate postures. They affect between 1% and 3% of the working-age population, with a high prevalence between 40 and 50 years of age, having significant economic and healthcare repercussions on the health system, as a result of sick leave.

This study aims to assess the efficacy of SIS, combined with a therapeutic exercise program of physiotherapy and health education in epicondyalgia in the adult population. There is little evidence on the effectiveness of the SIS. According to the literature searched, we are aware of some publications on the effectiveness of the SIS but only case studies or studies with a very small population; both in epicondylgia and in other conditions. Scientifically, showing the efficacy of a treatment with case studies is complicated by the small sample size and inconclusive results. For this reason, we highlight the importance of carrying out a study with a larger sample in order to obtain more significant results.

SIS is an innovative and non-invasive therapeutic technology. It creates a high-intensity electromagnetic field that interacts with the tissues of the human body. The 2.5 Tesla electromagnetic field causes strong muscle contractions, helping to control pain. Being a non-invasive system, it is well tolerated by patients and minimizes complications resulting from other treatments. This makes it easier to apply and adhere to the treatment of patients with this system. The fact that it is not an invasive therapy will allow us continuity, safety and cohesion of the study sample.

Its effects include the reduction of acute and chronic pain, the improvement of joint mobility and muscle strengthening in cases of tendinopathies, among others. Its implementation could accelerate recovery from this pathology and improve variables such as pain, mobility and strength. The aim is to show its effectiveness and cost-efficiency, contributing to the reduction of the number of work disabilities and their duration, treatment and recovery time, as well as expenditure on pharmacological treatment. In this way, it will be possible to maintain a sustainable, efficient and equitable public health system, offering quality care to all users who present this problem.

This study will be multicentre, with the participation of three Rehabilitation and Physiotherapy Services (Mataró-Barcelona, Barcelona-Sant Andreu and Barcelona-Drassanes). One of the purposes of carrying out this project in three different centres is to be able to obtain a larger sample and obtain more significant results in order to respond to the gap in the current scientific literature.

In line with the Strategic Plan 2023-2026 of the Catalan Institute of Health (ICS), in the field of Primary Care (PC), the North Metropolitan Territorial Management is characterised by its capacity for innovation. This new Plan will accompany us as a key tool to develop the skills of the professionals participating in this project to the maximum, giving special value to internal talent, applying the SIS as an innovative tool in lateral elbow tendinopathies to achieve the desired results.

The Strategic Plan 2023-2026 is aligned with the Health Plan of Catalonia 2021-2025 and is the instrument and reference framework for all public actions in the field of health within the scope of the Generalitat.

In clinical practice, this project is in line with the mission, vision and values redefined in the new Strategic Plan. Its mission is to promote and improve the health and quality of life of citizens, through comprehensive and integrated health care, generating and sharing knowledge. In terms of vision, it aims to be recognized by society as a people-centred organisation, for our excellent service, for our capacity for problem-solving, transformation and innovation, and for the commitment of our professionals. Finally, special value is given to professional competence, the commitment and co-responsibility of professionals in health outcomes, humanity and ethics, equity and sustainability in resource management.

The aim is to update the treatment protocol in relation to tendinopathies, adapting it to reality and current needs, offering person-centred care, with an excellent service, with the capacity for resolution and innovation, and with the commitment of the different professionals involved in the project.

This study will provide evidence for the incorporation of a new therapeutic tool into clinical practice, improving the efficacy of treatment, reducing costs and offering a better experience to patients in primary care.

The SIS is presented as a key tool for developing a more sustainable and advanced healthcare, putting the company at the forefront of innovation in physiotherapy and rehabilitation, and the patient as the protagonist of their recovery process.

Hypothesis/s

The combined therapy of the SIS, with a therapeutic exercise program of upper limb physiotherapy and health education, will promote the reduction of pain, improve the mobility and functionality of the affected limb, increase grip strength, facilitate the return to activities of daily living (ADL), as well as the perception of improved quality of life in people with lateral elbow tendinopathies.

Objective(s) (General and specific)

Main objective: To evaluate the effectiveness of SIS combined with a therapeutic exercise program of physiotherapy and health education in cases of lateral tendinopathy of the elbow in people aged 18 years or older, compared to the application of SIS with a non-therapeutic dose and the performance of conventional therapeutic exercise and health education treatment.

Secondary objectives

- Decrease pain in the affected upper extremity.
- Increase the active mobility of the upper limb, in cases where it is affected.
- Improve the functionality of the affected limb to return to its daily activity.
- Increase the grip strength of the affected limb.
- To analyze changes in quality of life, pre and post treatment, in people suffering from lateral elbow tendinopathies.
- To compare sociodemographic and baseline characteristics of the intervention group and the control group.
- Quantify the number of treatment sessions until discharge (% of absenteeism).
- Compare the amount of pre- and post-treatment pharmacological treatment.
- To evaluate the number and duration of temporary work disabilities before and after treatment.

Methodology

Design of the studio

The design of the multicenter study consists of a randomized, experimental, prospective, triple-blind clinical trial of the principal investigator, the evaluator and the user. With a control group (SIS with non-therapeutic dose, therapeutic exercise program and health education) and intervention group (SIS with therapeutic dose, therapeutic exercise program and health education), on the adult population derived from lateral elbow epicondyalgia to one of the three Rehabilitation and Physiotherapy Services (Mataró, Sant Andreu-Barcelona and Drassanes-Barcelona). The three centers are in the field of Primary Care, of the ICS.

The study is prospective, with data collection at the beginning of the treatment, at the end of it, 3 and 6 months after the end of the treatment.

Scope and period of study

The project will be multicentre. It will take place in three Rehabilitation and Physiotherapy Services (Mataró, Sant Andreu and Drassanes), in the field of Primary Care of the ICS. It is intended to start the intervention in September 2025 and continue during 2026, uninterruptedly, until the entire calculated sample and its post-intervention controls are reached.

Reference population

People aged 18 years or older, affected by pain, acute or chronic, in the lateral epicondyle of the elbow.

Study population

People attended to by the three Rehabilitation and Physiotherapy Services (Mataró, Sant Andreu and Drassanes), referred to the Family Doctor, the Rehabilitation Doctor, the Traumatologist or the Rheumatologist, with a diagnosis of epicondyllgy.

Once these people have been detected, they will be explained the Rehabilitation treatment and, after delivering the information sheet to the patient (Annex 1) and subsequently signing the informed consent (Annex 2), informed consent for the transfer of images (Annex 3) and the commitment sheet for assistance to the treatment and controls (Annex 4), they would participate in the study. They will also have the Waiver Form, if applicable (Annex 5).

The sample will be randomly selected in the intervention group or in the control group.

Inclusion criteria

- Be 18 years of age or older.
- Be diagnosed with lateral epicondyalgia of the elbow, by the Family Doctor, Rehabilitation Doctor, Traumatologist or Rheumatologist.
- Referred to one of the three Rehabilitation and Physiotherapy Services (Mataró, Sant Andreu and Drassanes).
- One or both positive exploratory maneuvers (Cozen and Mill).
- Agree to be part of the study, by reading the patient information sheet (Appendix 1) and subsequent signing of the informed consent (Appendix 2) informed consent for the assignment of images (Appendix 3).

Exclusion criteria

- Medial epicondyalgia of the elbow.
- Recent traumatic history, in a period of less than 6 months.
- Limitation of more than 20º of the passive joint balance.
- Infiltration in the affected elbow 6 weeks prior to the first visit.
- Systemic inflammatory, autoimmune, infectious or tumour disease.
- Pregnancy.
- Metal implants in the affected elbow area.
- Pacemakers or defibrillators.
- Frohse's arch syndrome (compressive neuropathy of the motor branch of the radial nerve).
- Blood clotting disorders.
- Cognitive or sensory difficulty that prevents participation in the proposed treatment.
- Central sensitization syndrome (Fibromyalgia, Chronic fatigue,...).

Sample size and sampling procedure

Accepting an alpha risk of 0.05 and a statistical power greater than 0.8 in a bilateral contrast, 93 subjects in the intervention group and 93 in the control group are required to detect as statistically significant the difference between two proportions, of at least 20% in the worst case for the outcome variables.

Adding 20% to the result obtained, the total sample will be 224 users, and therefore, 112 users affected by pain in the lateral epicondyle of the elbow, in each of the two groups.

The sample will be recruited by referrals made by the family doctor, the rehabilitation doctor, the traumatologist, or the reference rheumatologist.

Once the sample size is achieved, the recruitment of users for the study will end.

Simple randomized assignment will be performed, with the same proportion to the GI and the CG, using an online random numerical sequence generator to two groups, by generating random numbers in Excel.

The randomization sequence will be carried out by the principal investigator (PI), who will not participate in either the intervention or the data collection.

The assignment will be hidden and opaque envelopes will be used to minimize selection bias. The PI will deliver the opaque envelopes to the evaluators. These, after evaluating the participant, will draw a random envelope and deliver it to the TCAI staff along with the participant's data. The evaluator will generate a treatment form with the indication "SIS Study". TCAI staff will open the envelope to find out which group each user is assigned to. They will schedule the start of the treatment with Physiotherapy and will contact you by phone to inform you of the day and time of the start of the treatment. They will give the assigned physiotherapist the sheet with the sessions scheduled for each patient together with the envelope that will indicate which of the two groups they will be assigned to.

The GIS staff will schedule the subsequent follow-up checks with the evaluators for both groups.

The evaluators are masked, since they do not have the randomization sequence.

The project is presented as a triple blind of PI, evaluators and users. The blinding of the physiotherapist is ruled out.

They will be randomly distributed to the Intervention Group and the Control Group.

- Intervention Group (IG): application of the Super Inductive System accompanied by a kinesitherapy and patient education protocol.
- Control Group (CG): application of the Super Inductive Placebo System (with non-therapeutic dose: 10 minutes at 1 Hz, 59-second pause and intensity of 5-10%) accompanied by the same kinesitherapy and patient education protocol.

The frequency of the treatment will be 2 weekly sessions with a total of 8 sessions.

The conventional treatment applied so far to the three Rehabilitation and Physiotherapy Services consisted of teaching a protocol of specific exercises accompanied by education to the patient.

The SIS equipment used for the GI will be the BTL-6000 Super Inductive System Elite, present in the three Rehabilitation and Physiotherapy centres.

Control will be carried out at the beginning and end of the treatment and follow-up at 3 and 6 months after the treatment.

Dependent and independent variables

Outcome measures will be carried out on the following quantitative variables: pain, joint mobility, grip strength, functionality and quality of life.

The evaluator has the Patient Information Sheet (Annex 1), the Informed Consent (Annex 2), the Informed Consent for the Transfer of Images (Annex 3), the Commitment Sheet for Assistance to Treatment and Controls (Annex 4), the Waiver

Sheet (Annex 5), the Data Collection Sheet (Annex 6), the Adverse Effects Collection Sheet (Annex 7), the assessment scales used (Annex 8) and the measuring instruments (Annex 9).

To measure the intensity of pain, the **Visual Analogue Scale (VAS)** will be used. Its simplicity and ease of use make it a widely used tool. It consists of a straight line, 10 cm long, with ends that represent the limits of pain (ranging from "painless" to "the worst enduring pain"). The person is shown a line with two clearly defined ends. The person marks a point on the line that corresponds to the intensity of the pain they feel at that moment. The position of the mark is measured and converted into a numerical value ranging from 0 to 10 (33).

The manual pressure algometer (PAIN TEST TM FPX 50) **will be used** as a device to measure pain sensitivity in response to an applied pressure. It is a useful instrument in research to assess the perception of pain in different parts of the body; in our case, in the affected elbow. This measuring instrument assesses pain accurately. The algometer applies a controlled progressive pressure perpendicular to the skin and muscle using a 1 cm2 head until the participant indicates to the evaluator the moment when he/she begins to feel pain. The pressure applied at that time is recorded as a measure of pain sensitivity. The average values of three consecutive measurements will be taken and compared with the opposite side lateral. Algometry has demonstrated excellent reliability (ICC 0.91) among examiners (9).

The **manual goniometer** will be used to measure the angle of movement of the elbow joint. It is an instrument with two moving branches and a scale graduated in degrees. The evaluator places the arm in a neutral position, above the elbow joint, and measures the angle of movement in different directions (flexion, extension, pronation and supination). It is a simple clinical tool to use (34,35).

With the **JAMAR Hydraulic Dynamometer**, the isometric grip force of the hand of the affected upper limb will be measured in kilograms. Its hydraulic system features a dual scale (pounds and kilograms) to show isometric gripping force (11). This dynamometer is known for its accuracy and reliability, and is considered the "gold standard" in the measurement of gripping force. It uses a measurement range of 0 to 90 kg (0 to 200 IBS). It has an adjustable handle to be placed in 5 different positions (from 35 to 87 mm). It is performed in a sitting, with the back straight and the feet touching the ground. The elbow will be located at 90º of flexion and in a neutral pronosupination position, attached to the body, with the wrist in a neutral position (36). The participant will be encouraged to squeeze the device as hard as possible and three measurements will be made resting 5 seconds between each of them. The test-retest reliability of this handgrip test with this type of dynamometer is very high (r=0.88-0.93) (37).

Upper limb functionality will be measured with the **QuickDash** (*Disabilities of the Arm, Shoulder, and Hand*) questionnaire. It is a self-administered questionnaire that is used to assess the impact of musculoskeletal disorders of the upper extremities. This questionnaire is an abbreviated version of the DASH and consists of 11 items that measure the patient's functional capacity and symptoms during the last week.

Assesses the difficulty in carrying out daily activities, work, social or family relationships, as well as pain and difficulties in resting. The items of the QuickDASH questionnaire are as follows: 1. Opening a jar with the lid closed, 2. Performing heavy household chores (mopping the floor, cleaning windows), 3. Carrying a shopping bag or briefcase, 4. Washing one's back, 5. Using a knife to cut food, 6. Perform recreational activities that require effort with the arm, shoulder or hand (playing golf, tennis, etc.), 7. Difficulty in social activities with family, friends or groups, 8. Limitation in work or other daily activities due to the problem in the arm, shoulder or hand, 9. Pain in the arm, shoulder or hand, 10. Tingling or feeling of needles in the arm, shoulder or hand, 11. Difficulty sleeping due to pain in the arm, shoulder or hand. The possible answers range from values 1 (no difficulty/problem) to 5 (incapable/very much pain). The result of the questionnaire is calculated on a scale from 0% (absence of disability) to 100% (severe disability). The average of the answers is calculated, 1 is subtracted from the total and multiplied by 25 to obtain a percentage ratio of the degree of disability. This questionnaire showed a test-retest reliability assessed with Lin's coefficient of agreement of 0.80 and an internal consistency greater than 0.9 (38).

Health-related quality of life will be measured with the **EQ-5D-5L questionnaire** (39). This quiz is an improved version of the EQ-5D-3L, introduced by the Euro-Qol Group in 2009 to increase the sensitivity of the instrument and reduce ceiling effects. The EQ-5D-5L has demonstrated its efficacy, reliability and discriminatory capacity in multiple pathologies and populations (40). It consists of five dimensions: mobility, self-care capacity, daily activities, pain/discomfort and anxiety/depression. Each dimension has five levels where participants must assess how they perceive that dimension at the moment: no problems, minor problems, moderate problems, serious problems and extreme problems. In addition, it uses the Visual Analog Scale (VAS) to record the patient's self-rated health on a vertical scale, where the ends are labeled "The Best Health You Can Imagine" and "The Worst Health You Can Imagine" (41). The patient indicates their state of health by checking the box next to the most appropriate statement in each of the five dimensions. The digits for the five dimensions can be combined into a five-digit number that describes the patient's state of health. The Value Calculator Index 1.1 (42) is used.

Pain will be considered as a dependent variable and the rest of the variables will be treated as independent.

Sociodemographic variables of the users participating in the study will be collected as covariates: age, sex, educational level, marital status, cohabitation, profession, dominant hand, affected limb, health history, temporary disability situation and start date, reference Primary Care Center, origin of the referral, medical diagnosis, duration of symptoms, sports practiced, use of orthopedic elements for the elbow, Diagnostic tests performed and date of performance, pain-related pharmacological treatment.

A record will be made of the possible adverse effects that may appear during the treatment with the SIS and adherence to the treatment in relation to the exercises.

Table 1: Summary of the study variables

VARIABLE	DESCRIPTION	VARIABLE TYPE	MEASURING INSTRUMENT	VALUES
Age	Age of participants, in years	Discrete quantitative	Questionnaire	years
Gender	Gender/sexual condition of the participants	Qualitative	Questionnaire	Male Female Others
Marital status	Administratively recognised cohabitation situation at the time of the interview	Qualitative	Questionnaire	Single Married Divorced Separated Widower
Coexistence	Cohabitation situation in the home where you reside	Qualitative	Questionnaire	Saw solo Live as a couple Live with the family Live with a caregiver
Educational level	Higher educational level, completed	Qualitative	Questionnaire	Illiterate Can read and write Primary education Secondary education University studies
Employment	Paid activity you carry out in a job	Qualitative	Questionnaire	Type of activity
CAP of reference	Primary Care Centre (Family Doctor and Nurse)	Qualitative	Questionnaire	Assigned EAP name
Rehabilitation and Physiotherapy Service	Center where the intervention will be carried out	Qualitative	Questionnaire	Mataró Barcelona-Sant Andreu Barcelona-Drassanes
Upper limb affected	Arm affected and limited to perform the function normally	Qualitative	Questionnaire	Right Left Right and left
Dominant hand	Hand that he uses more frequently and skillfully to perform everyday tasks	Qualitative	Questionnaire	Right Left Right and left
Use of orthosis for the affected elbow	Use of devices	Qualitative	Questionnaire	Yes Not
Time of use of the orthosis	Time, in months, of the use of orthosis. The year prior to the start of the study and during the follow-up	Quantitative	Questionnaire	Months
Health history	Presence, at the time of the interview, of illnesses. Presence of health problems of interest, prior to the interview	Qualitative	Questionnaire	Open Response
Temporary Disability Situation	Situation of temporary disability due to the reason for the study	Qualitative	Questionnaire	Yes Not
Time of temporary disability	Time, in months, of temporary disability	Quantitative	Questionnaire	Months
Pharmacological treatment	Current pharmacological treatment and dose, related to and with epicondyalgia	Qualitative	Questionnaire	Open Response
Physical activity and sports	Physical activity	Qualitative	Questionnaire	Yes Not
Types of physical activity and sports	Specify the type of physical activity	Qualitative	Questionnaire	Open Response
Time spent on physical activity and sports	Specify the time spent on physical activity and sports per week	Qualitative	Questionnaire	In minutes

Subjective pain	Assess the pain of the affected elbow with the Visual Analogue Scale (VAS)	Quantitative	EVA	0-10
Pressure pain threshold	Assess pressure pain in the affected elbow, with the Algometer	Quantitative	Algometry	Newtons (N) o Kilograms-força(Kgf)
Joint mobility	Assess the joint mobility of the elbow with the manual goniometer	Quantitative	Goniometry	Flexo/extension and prono/supination degrees
Hand grip strength	Measuring the hand gripping force	Quantitative	Dynamometry	Kilograms (Kg)
Upper limb function and disability	Resposta al qüestionari QuickDASH (Disabilities of the Arm, Shoulder and Hand)	Quantitative	QuickDASH Quiz	Answer to the questionnaire
Quality of life	Answer to questionnaire EQ-5D-5L	Quantitative	Questionnaire EQ-5D-5L	Answer to the questionnaire
Sessions held	Number of sessions carried out out out of the total	Quantitative	Questionnaire	x/8
Adherence to treatment	Of the total number of days of the week, how many have performed the exercises	Quantitative	Questionnaire	%
Adverse effects	Collection of possible adverse effects	Quantitative	Questionnaire	Open Response
Assessment of blinding	Do you think that the SIS has been applied to you with a therapeutic or non-therapeutic dose?	Qualitative	Questionnaire	Yes Not

Intervention

The participants of the Intervention Group (IG) will receive a treatment that will consist, firstly, of carrying out a program of therapeutic physiotherapy exercises (Annex 10). This protocol is based on the performance of a series of exercises that will be guided by the assigned physiotherapist. The professional will carry out a weekly assessment to determine the most appropriate progression of the exercises for each participant. This progression, in relation to the force performed and the joint range, will be adjusted according to the intensity of the pain described by the user. The worksheet will be provided to the participant so that he has visual support of the drawings and the explanation, to be able to carry out at home. The recommended frequency will be four days a week. A guideline of 2 sets of 10 repetitions has been established for each exercise. The protocol ends with a self-massage of the affected muscles.

On the other hand, you will be provided with the health education sheet (Annex 11) which includes a brief explanation about epicondylitis, how to prevent this ailment and the recommended recommendations to improve quality of life.

Finally, the SIS will be applied with the pre-established program for elbow tendinopathies. The duration of the program is 10 minutes. The intensity applied will be set by the user, according to the motor tolerance threshold of each one. It has been decided to apply it after the exercises and health education, due to the analgesic effect it provides.

For the CG, the SIS will be applied with a non-therapeutic dose (10 minutes, with a frequency of 1 Hz, a pause of 59 seconds and an intensity of 5%) accompanied by the same therapeutic exercise program of physiotherapy (Annex 10) and health education (Annex 11).

The SIS equipment used for the GI and GC will be the BTL-6000 Super Inductive System Elite, present in the three Rehabilitation and Physiotherapy centers (Mataró, Barcelona-Sant Andreu and Barcelona-Drassanes).

The frequency of treatment will be 2 weekly sessions with a total of 8 sessions. According to the regulations of the centers where the intervention will be performed, the missed sessions are not recovered. For this reason, a record will be made at the end of the treatment, of the sessions carried out. In this way, the percentage in relation to absenteeism will also be calculated (Annex 6).

The conventional treatment applied so far to the three Rehabilitation and Physiotherapy Services consisted of teaching a protocol of specific exercises accompanied by education to the patient. Therefore, GC participants will not stop receiving pre-established treatment prior to the study. In addition to receiving conventional treatment, the SIS will be applied with a non-therapeutic dose.

Data collection and sources of information

The principal investigator of the study (PI) will hold an informative meeting with the participating professionals, and will provide them with the appropriate material. The evaluators will be given the questionnaire for the first visit. The physiotherapists will be given the guidelines for performing the intervention; SIS programmes for both groups, kinesitherapy protocol (Annex 10), health education sheet for the patient (Annex 11) and the exercise record carried out (Annex 12). The administrative staff or GIS (Management and Services) staff and the TCAI (Nursing Assistant Care Technician) will explain the steps to follow once the patient has already been evaluated.

Firstly, the user is referred by the Family Doctor, the Rehabilitation Doctor, the Traumatology or Rheumatology Service to one of the three Rehabilitation and Physiotherapy Services of Primary Care of the ICS (Mataró, Sant Andreu or Drassanes).

The referrals are reviewed by the Head of Service of the centre. They will carry out an administrative task for the administrative staff, of referrals with the medical diagnosis of lateral epicondylgia, so that a face-to-face visit is scheduled in the agenda of the case evaluator (in this case a physiotherapist who will act exclusively as an evaluator and will not perform the intervention).

The administrative staff will schedule the visit and call the user to provide a date and time.

The evaluator will have an exclusive agenda to visit the potential cases that will be part of the study. The visits will be carried out in person and individually in a consultation of one of the three Rehabilitation and Physiotherapy Services.
It is estimated that the duration of the visits per person will be 45 minutes. The evaluator will use the eCAP (Primary Care and Coordination Team) program. It is a clinical information system used in primary health care in Catalonia. This system allows healthcare professionals to manage user information efficiently, including medical records, e-prescriptions, appointments, and other relevant data. It facilitates coordination between the different levels of care and improves the quality of health care provided to users. In addition, it allows healthcare professionals to access user information quickly and securely, contributing to better clinical decision-making.

During the visit, the evaluator will collect data (Annex 6) and explore the user. You will pass the following assessment scales: pain results measured with the manual pressure algometer (PAIN TEST TM FPX 50) and the EVA (Visual Analogue Scale), joint balance/mobility (flexion, extension, pronation and elbow supination) measured with goniometer, grip strength with the JAMAR hydraulic dynamometer, functionality with the QuickDASH questionnaire (self-administered scale, to assess upper limb function) and quality of life with the EQ-5D-5L questionnaire (self-administered, standardised scale that assesses health-related quality of life).

Adverse effects will be collected by means of a questionnaire (Annex 7).

All assessments will be carried out at the beginning and end of the treatment, and controls at 3 and 6 months after the end of the treatment.

The suitability of the participants will be assessed according to the inclusion criteria. At the end of the visit, if you meet the inclusion criteria, you will be offered the opportunity to participate in the study, explaining what it consists of and giving the information sheet to the patient (Annex 1) and informed consent (Annex 2).

In the event that you sign the consent and agree to participate in the study, you will deliver the signed consent to the TCAI staff, who carry out administrative tasks and schedule the treatment in the physiotherapy agenda.

The evaluator, using opaque envelopes, will make the participant choose one, who will add it to the treatment sheet. The physiotherapists in charge of performing the intervention will be the only ones who have the list with the randomization sequence to distribute the different participants in the IG or GC. This list will be provided by the Research Support Unit (USR).

The TCAI staff will contact the user by telephone to specify the day, time and professional to carry out the intervention. At no time will the user be informed which group he belongs to. The TCAI staff will give the physiotherapist who performs the intervention, the opaque envelope specifying which group the user has been in, together with the sheet of scheduled sessions. This information on assignment to the GI or GC will only be known by the physiotherapists who will perform the intervention. Neither the IP nor the evaluator nor the user will have this information.

The research team will have a waiver sheet to provide participants with if they do not wish to continue being part of the study (Annex 5).

REDCap (Research Electronic Data Capture) will be used as a tool to manage the data. It provides a secure and flexible environment for data collection and management, facilitating collaborative work and guaranteeing information privacy and security. Access to the USR of the IDIAP Jordi Gol will be requested.

Data analysis, implementation, masking and statistical methods

Descriptive analysis of the characteristics of the sample: means, standard deviations, medians and interquartile ranges. The frequencies and percentages for the categorical variables will be calculated.

Parametric and non-parametric tests will be used to analyse the data. The distribution will be analyzed using the Kolmogorov-Smirnoff or Shapiro Wilk test, depending on the sample size.

With the T-Student or U Mann Whitney test, the basal demographic variables of the two groups will be compared, depending on the distribution of the variables.

Chi square will be used for categorical tests of only two categories or linear square chi for those of three or more categories.

For the analysis of before-and-after changes within groups, T Student will be used for paired or Wilcoxon data, depending on the distribution of continuous or discrete quantitative variables.

We will evaluate with the ANOVA test of repeated measures or Friedmann. Bonferroni tests will be carried out to evaluate the changes during the follow-ups.

The applicability criteria of each test will be checked beforehand and if it is not possible to apply, the equivalent non-parametric variables will be used or the necessary transformations will be made in the variables. In the initial multivariate models, in order to demonstrate the effect of the intervention on the outcome variables, the variables that are significant in the bivariate analysis will be introduced at the significance level of 25% and the variables considered clinically relevant. Confusion, possible interactions and collinearity will be studied. For all hypothesis contrasts performed to assess association between variables, an alpha level of 0.05 ($p<0.05$) will be considered statistically significant.

Adverse effects will be analyzed using contingency tables, Chi-square tests, or Fisher's exact text.

Finally, a descriptive analysis of the adverse effects that may appear will be carried out.

Pharmacovigilance

There is no use of medications.

Ethical considerations and confidentiality of data

The study will be carried out in accordance with the accepted international ethical standards of Good Clinical Practice (CPMP/ICH/135/95), the principles established in the Declaration of Helsinki (last amendment, Fortaleza-Brazil, 2013), RD 1591/2009 and Circular No. 07/2004 regulating clinical research with medical devices.

Likewise, the study will be carried out in accordance with General Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of data and on the free movement of such data and Organic Law 3/2018 of 5 December on the Protection of Personal Data and the Guarantee of Digital Rights.

On the other hand, it will be subject to review by the CEIC (Clinical Research Ethics Committee) of the Catalan Institute of Health (ICS) of reference (IDIAP Jordi Gol).

Data protection, the right to withdraw voluntarily without any penalty and the obtaining of Informed Consent (CI) by participants will be ensured.

According to the laws mentioned above, all the data collected will be encrypted and stored in a document in the Office 365 folder in the cloud of the ICS server. This ensures compliance with all European safety standards. The custody of these files will fall to the principal investigator. The research team, the medical authorities, the ethics committee and the staff authorized by the sponsor will have access to the personal information of the participants. All people participating in the study will receive the Patient Information Sheet (FIP) and sign the IC. This form specifies that participation in the study is voluntary, that the confidentiality of the data is guaranteed and that each participant has the right to withdraw consent at any time and without explanation. This data will only be accessible to members of the research team. Once the data collection process is finished, all of them will be anonymized, eliminating any personal information of each participant.

The data will be kept for 5 years once the end of the project has been completed and communicated. No communication of personal data is contemplated, beyond those provided for by law. Nor will international data transfers be carried out.

Data processing and protection

All data will be processed in accordance with the Data Protection Act 2021 and stored securely on a storage device with restricted access. All recorded clinical outcomes will be anonymized by giving each participant a random code number at the beginning of the study, which has nothing to do with personal information, to protect confidentiality. The test data will be stored on storage devices that can only be accessed by researchers.

The information will be recorded in encrypted form and stored in a protected database on computers of the Catalan Institute of Health, and the data that allows its decoding will be in another file with a password accessible only to researchers. The Catalan Institute of Health acts as responsible for processing the data within the framework of this study, since the project's database will be hosted on the ICS servers.

The variables necessary to be able to develop the study will be obtained directly from the project participants through their consent.

In this study there will be no international transfer of data nor is the dissemination of data to third parties planned. The study does not include any of the following risk situations for data processing: automated decision-making, use of artificial intelligence, use of data exploitation techniques with big data technology, use of biometric systems or use of geolocation systems. There will be no identification of processing that poses a high risk to the rights and freedoms of the data subjects.

Each participant will be assigned a numerical code, which will not be related to the history number or any identifying data of the patient, therefore, the processing of the data will be carried out anonymously by the researchers. This code will be assigned by the head of the Centre, Consultation, Department or Clinical Unit. In the event that the results of the study are used, for teaching, research and/or publication purposes, the proper coding of personal data will always be respected, so that the subjects of the research will not be identified or identifiable.

The holder of the personal data may exercise the rights of access, rectification, cancellation and opposition to the processing of personal data, and revocation of consent, under the terms provided for in the applicable regulations.

Additional procedures derived from the study

The participants for this study come from the centres and institutions attached to the rehabilitation services of Barcelona and Maresme by the Catalan Institute of Health (Department of Health of the Generalitat de Catalunya). After each participant has been duly informed about the study and their rights, and meeting the eligibility and exclusion criteria; You will be invited to participate in this study, and you will be explained the randomization process.

All information related to the study and the data protection system will be explained verbally and provided in an information document to the participant (Annex 1). Once all questions have been answered and eligibility has been confirmed, those who declare interest in participating will be asked to sign the informed consent form (Annex 2). A copy of the document will be given to the participant and another copy will be kept by the PI.

Difficulties and limitations of the study

This type of study has some limitations to take into account.

An important barrier can be the loss of participants due to non-attendance at treatment and/or follow-up check-ups, as a result of the appearance of health problems that force the intervention to be stopped, or due to lack of motivation or commitment. In order to cover these possible losses, 20% more participants have been added to the sample, adherence will be ensured by telephone by administrative staff when participants do not show up for the intervention sessions or the different follow-ups, and the commitment to attend will be signed, both at the treatment sessions and at the follow-up controls (Annex 4).

It is important to take into account the differences in the personal conditions of the participants: carrying out treatments parallel to our project, appearance of health problems, pharmacological treatments during the intervention, etc. This difficulty will be minimized by narrowing the exclusion criteria, carrying out careful data collection and follow-up interviews. We will keep this in mind to include it in the conclusions of the study.

The lack of supervision of the exercises at home must be considered. To minimize this limitation, the exercise protocol sheet will be provided with a QR that will give access to the videos of the exercises (Annex 10).
The cost of the material/personnel needed for the study (budget requested) could be a limitation to carry out the project going forward. To solve this, research grants will be requested in all possible calls.

Work plan

1st year

PREPARATION:

- Project design: January - February 2025.
- Literature review: January - March 2025.
- Feasibility analysis: January - February 2025.
- Prepare draft and report: January - March 2025.
- Obtain permits and Research Ethics and Integrity Committee (CEI): March - July 2025.
- Seeking funding: June 2025 – July 2026.
- Training of professionals: June - July 2025.
- Sample selection (convenience sampling): September 2025 – February 2026.
- Contact participants: September 2025 – February 2026.

EXECUTION:

- Interview with participants (Informed Consent (IC), Patient Information Sheet (FIP), Intervention Group (IG) – Control Group (CG) assignment): October 2025 – March 2026.
- Initial questionnaire-Intervention: October 2025 – March 2026.

2nd year

PREPARATION:

- Seeking funding: June 2025 – July 2026.
- Sample selection (convenience sampling): September 2025 – February 2026.
- Contact participants: September 2025 – February 2026.

EXECUTION:

- Interview with participants (Informed Consent (IC), Patient Information Sheet (FIP), Intervention Group (IG) – Control Group (CG) assignment): October 2025 – March 2026.
- Initial questionnaire-Intervention: October 2025 – March 2026.
- Follow-up 3 and 6 months after the end of the treatment: January 2026 – March 2027.
- Data collection and statistical analysis: January 2026 – April 2027.

3rd year

EXECUTION:

- Follow-up 3 and 6 months after the end of the treatment: January 2026 – March 2027.
- Data collection and statistical analysis: January 2026 – April 2027.
- Results: April - June 2027.

COMPLETION:

- Prepare results report: June - September 2027.
- Dissemination of the project's results (at the ICS, Congresses, talks, publications of scientific articles (at least one in a journal with quartile Q1 or Q2): October - December 2027.

The project schedule can be consulted in the Annexes section (Annex 15).

Experience of the research team

- **Carme Sánchez Mato:** Diploma in physiotherapy from the Ramon Llull-Blanquerna University (1998). Graduated in Physiotherapy from the University of Salamanca (2022).

  In 2006 he completed the Postgraduate Course in Paediatrics at the Ramon Llull University.

  In 2012 he completed a Master's Degree in Rehabilitation in Neurology at the Gimbernat University School.

  In 2024 she completed the Master's Degree in Research in Primary Care. Miquel Hernández University of Elche.

  She is currently processing the documentation to start the Doctoral Thesis.

  She has been working in the Rehabilitation and Physiotherapy Service of Primary Care of the Catalan Institute of Health (ICS) Mataró-Maresme since 2000. In 2016, the coordination of the Service began, combining healthcare tasks with management, teaching and research. In 2018 she took the exam for the position of Physiotherapist at the ICS.

  Her field of work is clinical practice, care management of 3 rehabilitation centers, teaching in the degree in Physiotherapy at the University of Vic-Central University of Catalonia and the Autonomous University of Barcelona and research.

  She is currently part of the research team of the PRECIOSA II-Badia Community Intervention Project and the project of Co-creation and application of a physiotherapy model in high-impact Primary and Community Care: Fisio-on APiC.

  It has been a benchmark in quality and patient safety for 10 years. Since 2012, she has been a member of the PAR I working group (Pact for Accessibility and Resolution of the Musculoskeletal System), where the care documents for the treatment of Low Back Pain, Gonalgia, Painful Shoulder and Osteoporosis have been developed.

  It coordinates the Maresme Interest Group and the Primary Care Commission, through the College of Physiotherapists of Catalonia. The main objective is the dissemination of the profession, organizing activities to promote health, therapeutic exercise and prevent the disease.

Since November 2022 she has been deputy secretary of the College of Physiotherapists of Catalonia.

He has received the certification of the three courses (basic, intermediate and advanced) on Information and Communication Technologies (ICT).

She has participated in different Programmes and campaigns promoted by the Department of Health: collaboration in the preparation of the Programme for the incorporation of physiotherapists for the promotion of the functioning and prevention of disability in primary and community care (2022), collaboration in the Project for the preparation of the new The Rehabilitation Plan of Catalonia: Comprehensive approach to functioning and disability (2023), member of the FisioAPiC Advisory Committee (from 2022 to present).

Has carried out various trainings in relation to the research project: research in primary care, design of research projects, dissemination of research results: oral communications and posters, drafting of protocols and funding funds for research projects, patient safety, updating in rehabilitation and physiotherapy processes, electrotherapy, therapeutic exercise in physiotherapy, updating in the treatment of tendinopathies in primary care.

She is a tutor for students of the Degree in Physiotherapy from six different universities, from 2004 to the present.

He has been a teacher of several training courses at the ICS, in relation to the updating of Rehabilitation and Physiotherapy processes.

He has collaborated in the preparation of 17 healthcare documents at the ICS (5 originals and 12 revisions), in relation to low back pain, gonalgia and homalgia.

He has participated in several national and international Congresses and Conferences, as a speaker and with the presentation of posters (22 oral communications and 23 posters).

Author of the publication of a scientific article with the title "Group intervention of subacromial syndrome in primary care". Rehabilitation. 48 - 2, pp. 82 - 92. Elsevier.

- **Dr. Anna Escribà Salvans:** In 2002 she began her academic career and in 2005 she obtained a diploma in Physiotherapy from the University of Vic – Central University of Catalonia (UVIC-UCC).

  Subsequently, in 2009, he obtained a Master's Degree in Occupational Risk Prevention; specialized in Ergonomics and Applied Psychosociology.

She combines her working life with taking courses in the field of physiotherapy and teaching in occupational health training centres. In 2016 she began teaching in the Degree in Physiotherapy at UVIC-UCC.

In 2017 she obtained the Postgraduate Course in Bodily Injury Assessment at the University of Barcelona. In 2019 the Official Interuniversity Master's Degree in Nervous System Sciences: Neurotoxicology, Neuropsychopharmacology, Neuromusculoskeletal Physiotherapy and Neurorehabilitation from the Rovira i Virgili University; of this, the presentation and defense of the master's thesis entitled: ¿Es la neurodinamia un tratamiento eficac para el dolor neuropático de extremidades inferiores?: Revisión systemática.

That same year, at the end of 2019, the doctoral programme "Comprehensive Care and Health Services" began. In November 2022, he defended the thesis entitled "Sarcopenia in geriatric residents of Osona according to the criteria of the European Working Group on Sarcopenia in Older People 2: observational study." directed by Dr. Javier Jerez Roig and Dr. Eduard Minobes Molina, obtaining the mention "laude".
At the same time, since 2018 she has been part of the Methodology, Methods, Models and Outcomes of Health and Social Science (M3O) research group, for which she has participated in several projects that have resulted in several scientific publications (13 in total). In line with the research trajectory, the line of research encompasses the areas of neurorehabilitation in the elderly and occupational health.

Throughout this career, she has combined her research career with teaching and management as Coordinator of external clinical practices of the Degree in Physiotherapy, which she began in 2016 teaching at the UVic-UCC in various subjects of the Degree in Physiotherapy. In addition, since 2018 she has tutored clinical internships and final degree projects and has assisted as a member of the panel of the defenses of these, in the Degree of Physiotherapy and collaborations as a member in tribunals of the Degrees of Nursing and Dietetics and Nutrition of the UVic-UCC.

Since 2023, he has been collaborating as a teacher at the FUB (University Foundation of Bages), University of Manresa. In June 2024 she reached the category of "Contracted doctor" and "professor at a private university" by the ANECA agency.

In all these years, he has attended and participated in National and International Congresses in different countries. She has received training courses in her specialisation, as well as in research and teaching innovation methodologies that complement the main areas of her profession; the academic, the researcher and the clinician.

- **Dr. Ramon Arroyo Aljaro:** Doctor of Surgery from the UAB with the thesis "Shoulder pain in the spinal cord injury. Relación con la discapacidad" defended on July 14, 2011 with a rating of excellent "Laude".

  He has 20 years of work experience at the ICS. Specialist in physical medicine and rehabilitation.

  He has been Territorial Clinical Director of Rehabilitation, Primary and Community Care Barcelona City since May 2022 to the present.

  Principal investigator of the research project "Descriptive study on distal radius and proximal humerus fractures in a Primary Care rehabilitation centre" in the 13th call for XB Research Modules of the Territorial Management of Barcelona City in 2021.

  Collaborating researcher of the research project, with a grant in the call for Research Modules of the Primary Care Area of Barcelona city of 2012, "Implementation of a multidisciplinary program in the treatment of the temporomandibular joint in the field of primary care" of March 25, 2014.

  Expert of the project "Shoulder pain: appropriate use of diagnostic imaging tests" developed by the Agency for Information, Evaluation and Quality in Health on March 28, 2011.

  Principal investigator of the research project, with a grant in the call for Research Modules of the Primary Care Area of Barcelona city of 2009, "Treatment of epicondylitis: prolotherapy versus usual physiotherapy treatment" of March 16, 2011.

  Collaborating researcher in the research project, with grant in the call for Research Modules of the Primary Care Area of Barcelona city of the year 2009, "Evaluation of the effectiveness of a program of balance and strength of lower limbs to improve the physical parameters of frailty in independent elderly people: Randomized controlled clinical trial." of March 16, 2011.

  Collaborating researcher in the research project, with a grant in the call for Research Modules of the Primary Care Area of Barcelona city of the year 2009, "Analysis of the current situation in primary care, detection and early referral of female urinary incontinence." of March 16, 2011.

  Collaborating researcher in the research project, with a grant in the call for Research Modules of the Primary Care Area of Barcelona city of 2008, "Improving health and quality of life postpartum" of December 31, 2009.

  SEP Award for the best work presented for "Repercussion of the shoulder in the spinal cord injury" at the "XXIV National Days of the SEP and XIII ASELME Symposium" of June 20-22, 2007.

  "Novartis" Award for the communication "Functional capacity of elderly patients who live alone in their home prior to a hip fracture" at the XVII Conference of

Update of the Catalan Society of Physical Medicine and Rehabilitation: Clinical exploration of the lower limbs of April 20, 2007.

Author of 4 book chapters and 9 publications in scientific journals.

- **Luisa Acosta Moreno:** Graduated in physiotherapy from the Gimbernat University School in 1994.

  She is coordinator of the Rehabilitation and Physiotherapy Service of the Catalan Institute of Health (ICS) of Sant Andreu in Barcelona and coordinator of the Primary and Community Care Physiotherapists (FisioAPiC) in Barcelona.

  In 1996 he completed the Postgraduate Course in Sports Physiotherapy and in 1998, the Postgraduate Course in Neuromotor Rebalancing of the Spine at the same University. In 2006 he completed the Postgraduate Course in Obstetric Physiotherapy and Pelvic Floor Reeducation at the International University of Catalonia.

  She completed the Master's Degree in "Community Physiotherapeutic Care" in 2016 and the Master's Degree in Electrotherapy: "Applied Electrostimulation for Physiotherapists" in 2018 at the Faculty of Physiotherapy of the University of Valencia.

  At the Institut de Formació Continua-IL3, in 2020, she will study the Master's Degree in "Comprehensive Management of Services in Primary Care, Social and Hospitals".

  He has completed various training courses in relation to the design of research projects.

  She has been a tutor for students of the Degree in Physiotherapy from 2004 to the present.

  She has participated in several research projects: Analysis of the current situation in primary care, early detection and referral of female urinary incontinence, Call for Research Modules of the Primary Care Area of Barcelona City (2009). Effectiveness of multidimensional group treatment of pain in disability, patients' perception of pain and illness and the use of active coping strategies, Rehabilitation Service of the CAP Sant Andreu in Barcelona (2013). Evaluation of a back pain intervention from Primary Care: health education programme in the school environment, rehabilitation service of the CAP Sant Andreu in Barcelona (2014). Effectiveness of shockwave treatment and specific exercise in subacromial syndrome compared to exercise alone. CAP Sant Andreu Rehabilitation Service in Barcelona (2014). Evaluation of a back pain intervention from primary care: health education programme in the school environment, Catalan Institute of Health (2014). Analysis of a back pain intervention from Primary Care: a health education programme in the school

environment. Rehabilitation Service of the CAP Sant Andreu in Barcelona (2015). "Short-term and long-term efficacy of active kinesitherapy group treatment in peripheral vestibular syndrome", Rehabilitation Service of the CAP Sant Andreu in Barcelona (2016). Chronic epicondylar pain: effectiveness of shockwave treatment. randomized clinical trial, Rehabilitation Service of the CAP Sant Andreu de Barcelona (2015). Early detection of prefragility and frailty states in primary care, Catalan-Balearic Society of Physiotherapy (2019).

He has participated in several Congresses and Conferences as a speaker or with the presentation of posters: Rehabilitation of the pelvic floor: a pathology to be treated in primary care, Health Plan of Catalonia 2011-2015 (2012). Analysis of the current situation in primary care, detection and early referral of female urinary incontinence, II Congress of the primary care field of Barcelona (2010). Presentation of the health education program in Primary Care for back pain in schoolchildren, II Conference of Rehabilitation professionals in Primary Care of the ICS (2014). Effectiveness of long-term rehabilitation in chronic temporomandibular pain, Conference of Rehabilitation professionals in Primary Care of the ICS (2014). "Tratamiento rehabilitador de la coxigodinia", I Conference of rehabilitation professionals in primary care centers of the ICS (2011). "Results of an exercise intervention for patients with gonarthrosis in Primary Care, X Trans-Pyrenean Congress of Physical Medicine and Rehabilitation (2009). " Electrostimulation of the posterior tibial nerve for the treatment of overactive bladder", II International Congress of the pelvic floor and pelviperineology (2011). Chronic temporomandibular pain. is rehabilitation effective?, Health Plan of Catalonia 2011-2015 (2013). "Medical-Physiotherapeutic Approach to Coxigodinias, XXVI Physiotherapy Conference of the ONCE and the III International Congress of "Physiotherapy in Pelviperineology: Present and Future" (2016). Evaluation of an intervention of back pain from primary care: health education program in the school environment", XVII National Congress SEDAP (2015). Medical-physiotherapeutic approach to coccygodynia, XIIth Congress of the Catalan-Balearic Society of Physiotherapy, Barcelona (2016). "Benefits of the rehabilitative treatment of chronic temporomandibular pain in the long term", 52nd Congress of the SERMEF (2014)." Manual treatment of coxigodinia", 48th National Congress of the Spanish Society of Rehabilitation and Physical Medicine SERMEF (2010). "Results of scar infiltration in post-surgical and postpartum pain", 55th Spanish Society Congress of Rehabilitation and Physical Medicine (2017). "Results of the rehabilitation treatment of coxigodynia", 55th Spanish Society of Rehabilitation and Physical Medicine Congress (2017). "Effectiveness of shockwave treatment in chronic epicondyle pain: randomized clinical trial, preliminary results", 55th Spanish Society of Rehabilitation and Physical Medicine Congress (2017). "Effectiveness of shock wave treatment in supraspinatus tendonitis: randomized clinical trial", 55th Spanish Society of Rehabilitation and Physical Medicine Congress (2017). "Program of preventive health education of back pain in schoolchildren in primary care, Primary care

marking course, XVII SEDAP Congress (2015). Webinar: how can physiotherapy help in multidisciplinary teams? Modality: Virtual (2022).

In 2014 he won an award at the II Conference of Rehabilitation Professionals in Primary Care of the ICS with the presentation of the work on Percutaneous Neuromodulation of the tibial nerve for urinary and fecal incontinence.

She has participated in different programmes and campaigns promoted by the Department of Health: virtual debate on trends in the health professions (2008), Protocol for the diagnosis and treatment of urinary incontinence in women; coordination between different levels of care (2020), Collaboration in the preparation of the Programme for the incorporation of physiotherapists for the promotion of functioning and the prevention of disability in primary and community care (2022), collaboration in the project for the preparation of the new The Rehabilitation Plan of Catalonia: Comprehensive approach to functioning and disability (2023), member of the FisioApic Advisory Committee (from 2022 to present).

Author of a book chapter: postural hygiene for teachers, childhood educating 0 to 6 years, issue of the magazine 188.

- **Mario Martín Sánchez:** Diploma in physiotherapy from the Gimbernat University School in 1993.

  With more than 30 years of experience as a Physiotherapist in the Rehabilitation and Physiotherapy Service of the Catalan Institute of Health (ICS) of Drassanes de Barcelona and coordinator of the Primary and Community Care Physiotherapists (FisioAPiC) in Barcelona, until 2024.

  At the Institut de Formació Continua-IL3, in 2020, she will study the Master's Degree in "Comprehensive Management of Services in Primary Care, Social and Hospitals".

  He has been a tutor for students of the Degree in Physiotherapy from 2001 to the present.

  He has carried out various trainings in relation to the design of research projects, bibliographic research and oral scientific communication and poster presentation.

  She has participated in several research projects: Improving quality of life in fibromyalgia syndrome. Study of two different therapeutic approaches, Catalan Health Institute, Primary Care Directorate L'Hospitalet (2000). Assessment of the effectiveness of the back school, Catalan Health Institute, Primary Care Directorate L'Hospitalet (2000). Implementation of a multidisciplinary

programme in the treatment of temporomandibular joint in the field of primary care, Catalan Institute of Health, primary care field, Barcelona city (2014). "Effectiveness of a dual physical exercise intervention and cognitive stimulation in frail elderly people", Institut Català de la Salut (2018).

He has participated in several Congresses and Conferences as a speaker or with the presentation of posters: Comparative analysis of two therapeutic strategies applied to gonarthrosis, IV Congress of the primary care field of Barcelona (2013). Comparative analysis of two therapeutic strategies applied to gonarthrosis, IV Congress of the Primary Care Field of Barcelona (2013). Analysis of the current situation in primary care, detection and early referral of female urinary incontinence, II Congress of the primary care field of Barcelona (2010). Proposal for a multidisciplinary treatment of TMJ, II Conference of Rehabilitation professionals in primary care of the ICS (2014). Two therapeutic strategies applied to gonarthrosis: comparative analysis, II Conference of Rehabilitation professionals in primary care of the ICS (2014). Implementation of a multidisciplinary programme in the treatment of temporomandibular joint in the field of primary care, Project XB Research Conference, primary care area Barcelona city (2014). "Program of education and functional rehabilitation in patients with mechanical algia in primary care", 3rd International Congress of physical activity sports for the elderly (2009). "Detection of signs of dysphagia in home care patients", XI National Update Days for Rehabilitation Physicians" (2012). Education and functional rehabilitation programme for patients with mechanical pain in primary care, Barcelona Primary Care Congress (2009). "Stress retraining in a primary care center for patients with severe COPD", 3rd International Congress of Physical Activity for the Elderly (2009). Treatment of temporomandibular dysfunction in a primary care rehabilitation service, VIII Conference on Speech Therapy and Dentistry (2015). Implementation of a multidisciplinary program in the treatment of the temporomandibular joint in the field of primary care, Research day, XB project. primary care area Barcelona city (2014). "Education and functional rehabilitation program for patients with omalgia in primary care", National Congress of the Spanish Society of Rehabilitation and Physical Medicine (SERMEF) (2008). Health education to prevent back pain: user assessment, IV Conference on quality in primary care of the ICS: tying heads (1998). Assessment of the effectiveness of the back school, awards for the improvement of primary health care in L'Hospitalet (1999). "Therapeutic education and functional rehabilitation: programs and methodology", 6th *Interdisciplinary World Congress of low back and pelvic pain* (2007).

She attended the XB project research day, in the field of primary care in Barcelona city (2014).

She was awarded different grants for research projects: analysis of the current situation in primary care, early detection and referral of female urinary incontinence, Barcelona city, 2009. Analysis of the current situation in primary

care, detection and early referral of female urinary incontinence, Barcelona city, 2009. Comparative analysis of two therapeutic strategies applied to gonarthrosis, primary care, Barcelona, city, 2012. Treatment of epicondylitis: prolotherapy versus usual physiotherapeutic treatment, primary care area of Barcelona city, 2009. Implementation of a multidisciplinary programme in the treatment of the temporomandibular joint in the field of primary care, Barcelona city, 2012.

He won awards for different projects: improving the quality of life in fibromyalgia syndrome. study of two different therapeutic approaches, awards for the improvement of primary health care of L'Hospitalet, 1999. "Education and functional rehabilitation program for patients with omalgia in primary care", 46th National Congress of the Spanish Society of Rehabilitation and Physical Medicine (SERMEF) 2012. Evaluation of the effectiveness of the back school, ICS, 1999. Improvement of quality of life in fibromyalgia syndrome. Study of two different therapeutic approaches, ICS, 1999. Awards for the improvement of primary health care in L'Hospitalet, Institut Català de la Salut, Dirección d'Atención Primària l'Hospitalet, 2000.

Applicability and practical usefulness of the results of the study

The results of this study may contribute to showing that the innovative technology of SIS can significantly accelerate the recovery process of musculoskeletal injuries, in our case, from lateral elbow tendinopathies. This application is especially valuable in the field of physiotherapy, where rapid recovery is essential for patients' quality of life.

SIS has proven to be an effective tool for the relief of chronic and acute pain.

The realization of this study will be able to show the results obtained with the application of this technology and will show that it can be used offering a non-invasive and safe solution.

The pain reduction and recovery acceleration provided by super inductive technology can have a positive and significant impact on the quality of life of our users. This technology will allow them to resume their daily activities more quickly, thus improving their overall well-being.

The results may suggest that this technology can be used to treat injuries and speed up their recovery, offering a valuable tool for the population.

The treatment of chronic pain through SIS can have a positive impact on health.

Our studies have shown that SIS is a safe and effective technology. There is a good tolerance to this non-invasive treatment, making it a viable and attractive option for a wide range of medical conditions.

The aim is to obtain evidence on the effectiveness and cost-efficiency of the technology, contributing to reducing the number of work disabilities and their duration, treatment and recovery periods, as well as spending on medicines.

This study will provide evidence to integrate a new therapeutic tool into clinical practice, improving the efficacy of treatments, reducing costs and offering an improved patient experience in primary care.

The SIS is presented as a key tool for developing a more sustainable and advanced healthcare system

In summary, the results of the study will provide the necessary evidence for the inclusion of this new therapeutic tool in clinical practice. This will improve treatment effectiveness, reduce costs and offer a better patient experience in primary care, positioning the company as a leader in innovation in this field.

Means available for the realization of the project

The Rehabilitation and Physiotherapy Units of Mataró, Sant Andreu and Drassanes have the population, space and material necessary to carry out the project.

Population: in order to achieve the study population calculated for this project, information sessions will be held for the family doctors of the different CAPs in the area and for the reference traumatologists, to inform them of the implementation of the project and, in this way, facilitate the referral of patients diagnosed with lateral epicondylalgia with specific criteria.

On the other hand, those users who have lateral epicondyalgia but are visited by our medical team for another reason may also be referred to physiotherapy to be part of the study.

Spaces:

A training room/classroom/consultation room is necessary, where the information session or training will be held for family doctors and specialists who will carry out the referrals, for the GIS staff who will contact the participants, for the professionals who will carry out the data collection, for the professionals who will carry out the randomisation and scheduling of the treatment and for the physiotherapists who will carry out the intervention. A bypass circuit will be presented (Annex 14).

In addition, a consultation will be used to carry out referral triage, evaluation of participants, telephone contact and treatment scheduling.

The intervention will be carried out in the room for the application of the SIS and the gym for carrying out the exercises.

Material:

Computer and telephone will be used for contact with the user.

For data collection, a computer, the manual pressure algometer (PAIN TEST TM FPX 50), the JAMAR hydraulic dynamometer, the manual goniometer, the EVA scale, FIP (Annex 1), the IC (Annex 2), the IC image assignment (Annex 3), the Commitment Sheet (Annex 4), the Data Collection Sheet (Annex 6) and the Assessment Scales (Annex 8) will be required.

For the intervention, a stretcher, chair, SIS (SIS Manual, Annex 13), exercise protocol (Annex 10), health education sheet (Annex 11), exercise record sheet (Annex 12) will be used.

Funding will be requested through grants for research projects by IDIAP Jordi Gol, by the College of Physiotherapists of Catalonia and funding sources. The thesis supervisor and co-supervisor have experience in obtaining this type of scholarship. In the event of not obtaining funding, the material can be loaned by the University of Vic – Central University of Catalonia.

Financial report and justification of the aid requested

Person Costs

Personnel necessary for the realization of the project:

Concept	Specifications	Expenses (€)
Personnel contracts	Rehabilitation physician for triage of referrals of the 224 participants	1.095,10
	Evaluator: Physiotherapist (448 hours for assessments at the beginning, end, 3 and 6 tables of the 224 participants)	4.125,54
	Physiotherapist: 72 hours of intervention	3.052,03
	GIS staff: 60 hours of telephone contact and scheduling of the 4 visits for the 224 participants	545,49
	TCAI staff: 30 hours of telephone contact, scheduling of the intervention and assignment to the groups, for the 224 participants	372,75

Requested quote

PRESUPPOSITION			
Concept	**Specifications**	**Expenses (€)**	**Subtotal (€)**
Personnel contracts	Rehabilitation physician for triage of referrals of the 224 participants	1.095,10	1.095,10
	Evaluator: Physiotherapist (448 hours for assessments at the beginning, end, 3 and 6 tables of the 224 participants)	4.125,54	4.125,54
	Physiotherapist: 72 hours of intervention	3.052,03	3.052,03
	GIS staff: 60 hours of telephone contact and scheduling of the 4 visits for the 224 participants	545,49	545,49
	TCAI staff: 30 hours of telephone contact, scheduling of the intervention and assignment to the groups, for the 224 participants	372,75	372,75
Material for the intervention	Computer equipment	599	599,00
	Manual pressure algometer (Pain test TM FPX 50)	395	395,00
	JAMAR Hydraulic Dynamometer	524	524,00
	Goniometer	1,47	1,47
	EVA	7,30	7,30
	Stationery material	150	150,00
Service Contract	Statistician who performs data analysis	2.551,31	2.551,31
	Translation and proofreading in English	439,00/article	878,00
	Publication of two articles in high-impact journals	1.107	1.107,00
	Presentation of results at national and international congresses: - IV International Congress of Physiotherapy (2026, Barcelona) - Others	70 1.010	1.080,00
Management Expenses	15 % (subtotal)		2.472,59
TOTAL			18.956,58

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Appendices

ANNEX 1: PATIENT INFORMATION SHEET

PATIENT INFORMATION SHEET (FIP)

Name of the candidate to participate in the study:

Within the framework of a PhD project by the Doctoral School of the University of Vic - Central University of Catalonia (UVIC-UCC), the physiotherapist Carme Sánchez Mato, as a PhD student, promoter of the study and principal investigator, carries out the research project with the title: **"Effectiveness of a combined therapy of the Super Inductive System (SIS) with a therapeutic exercise program of physiotherapy and health education in tendinopathies sides of elbows".**

Objectives of the study

The main objective of this study, for which we request your collaboration, is to evaluate the effectiveness of SIS in cases of lateral elbow tendinopathies in people aged 18 years or older. The application of the SIS will be combined with a program of exercises and health education, to reduce pain, improve the mobility and functionality of the upper limb, increase grip strength and evaluate the quality of life of those who suffer from this problem.

With this document we offer you information and invite you to participate in the study. You can ask any questions and request more information about any aspect that you do not understand. Do not give your approval and do not sign this document until you are satisfied with the answers to your questions.

The realization of this study has received the approval of the Research Ethics Committee of IDIAP Jordi Gol, which is responsible for guaranteeing the protection of the rights of the participants and that the methodology of the study is correct.

Why is this study carried out?

Epicondyalgia is a musculoskeletal disorder that causes pain and dysfunction in the upper extremity. It is related to repetitive movements of the elbow and hand, during sports and work or domestic activities, which require intense force in inappropriate postures, causing limitations in daily work and activities of daily living. Therefore, it constitutes a major public health problem.

The symptoms that occur with epicondylalgia are pain in the area of insertion of the muscles that insert into the elbow, affecting strength, functionality and quality of life.

SIS is an innovative and non-invasive therapeutic technology. It reduces acute and chronic pain, improves joint mobility and muscle strengthening, among others. Its implementation could accelerate the recovery from this pathology. The aim is to obtain evidence on its effectiveness and cost-efficiency, contributing to the reduction of the time of incapacity for work, treatment and recovery time, as well as the expenditure on pharmacological treatment.

What does the study consist of and what is expected of you as a participant?

To be part of the study, participants will need to answer questions asked by the evaluators and then a series of questionnaires with specific questions about the aspects to be evaluated. Then, he will have to go for 8 days for treatment, and will be evaluated again using the same questionnaires. Three and six months after finishing the program, he will be summoned again to answer these last questionnaires, again to see how he has evolved. The first visit will last approximately 45 minutes, the rest will last no more than 20 minutes. The treatment sessions last approximately 45 minutes.

A sample of users of three different Rehabilitation and Physiotherapy Services (Mataró, Sant Andreu de Barcelona and Drassanes de Barcelona) participated in this study, referred by the Family Doctor, Traumatologist, Rheumatologist or Rehabilitation Doctor or by the Traumatologist. The administrative staff has contacted you to arrange an appointment with the physiotherapist who will carry out the evaluation. In this visit you will be given the detailed information and you will be invited to participate in the research study.

Users will be divided into two groups. In one of them, an exercise program will be carried out to improve the mobility and strength of the muscles of the affected upper limb. They will be given a sheet with recommendations (health education) on the pathology and the SIS will be applied, with the pre-established program for tendinopathies and with an intensity according to the motor threshold of each patient. The other group will carry out the same exercise and health education program but the SIS will be applied with a non-therapeutic dose. Randomly, they will assign it to one group or another.

Both in one group and in the other, a total of 8 sessions will be held, with a frequency of two days per week. The days that you do not attend rehabilitation will have to be done at home. It will not mean more than 20 minutes a day.

If you have been included in the group in which the application of the SIS parameters are not therapeutic and the results of the study are beneficial, please note that in the future you could benefit from this project. The participants in this group will not fail to obtain the conventional treatment that, until now, has been applied to tendinopathies; that is, the exercise program and health education.

Their participation in this research study is completely voluntary. If during the development of the study you decide to withdraw, you can do so freely at the time you consider it appropriate, without any need to give explanations and without altering your relationship with the researchers and collaborators of the study for this reason.

Who can participate in the study?

All those people of legal age who have pain in the external lateral area of the elbow, referred by the family doctor, traumatologist, rheumatologist or rehabilitation doctor, can participate in the project. Reasons for exclusion from the study will be those people who have a recent traumatic history (less than 6 months), who have a limitation of passive mobility of the elbow, and have received infiltration in the affected elbow in the last 6 weeks, are carriers of pacemakers or metal implants in the affected area, have cognitive or sensory difficulty that prevents their participation in the proposed treatment or suffer some other affectation than their own. doctor or assessor considers it a difficulty for their participation.

What happens if I decide to participate in the study?

You should know that your participation in this study is voluntary and that you can choose not to participate. You can change your decision and withdraw your consent at any time without altering

your relationship with the doctor or physiotherapist or causing any prejudice to your care. If you decide to participate, with your signature, you would be accepting that the healthcare team and researcher responsible for being able to analyze your clinical history with the sole purpose of knowing what your current clinical situation is and what your evolution is during the follow-up of this study. With his participation, he will help the scientific community to better understand the influence of SIS on lateral elbow tendinopathies in order to be able to address them excellently in the future. For their part, they will receive the current treatment established by protocol for the management of their ailment.

Confidentiality of data

The results of the various tests carried out, as well as the documentation relating to him/her, are absolutely confidential and will only be available to the research team and the competent health authorities, where appropriate.

Publication of the results

The research team recognizes the importance and significance of the study and, therefore, is willing to publish the results in a journal, publication or scientific meeting to be determined. If you wish, the researcher responsible for the study will inform you of the results, as well as any other relevant data that is known during the study.

Information on confidentiality and data protection. How will your personal data be processed?

All participants will be assigned a code by which it is impossible to identify the participant with the answers given, fully guaranteeing confidentiality under the responsibility of the Catalan Institute of Health as data controller (hereinafter "the data controller").

The data that will be obtained through their participation will not be used for any purpose other than that explained in this research and will become part of a data file for which the principal investigator will be fully responsible.

This data will be collected, stored and protected through the use of the REDCap Web application. Only study researchers will be able to access it.

The processing of the data will be carried out in compliance with the "Regulation (EU) 2016/679 of the European Parliament and of the Council", of 27 April 2016, on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (GDPR), and the "Organic Law 3/2018, on Data Protection and Guarantee of Digital Rights", (LOPD-GDD).

In accordance with this law, you may exceed your rights of access, modification, opposition and cancellation of this data through the address of the Data Protection Officer (dpd@ticsalutsocial.cat) or by contacting Carme Sánchez, at CAP II Maresme, on 93 741 51 77, principal investigator of this project.

By signing this document, you expressly consent to your data being processed for research purposes within the framework of this project, in accordance with articles 6.1.a, 9.2.a of the GDPR. This data will be kept for 5 years once the end of the project has been completed and communicated. No communication of personal data is contemplated, beyond those provided for by law. Nor will international data transfers be carried out.

The publication and dissemination of the research results of the project will be carried out scrupulously respecting the anonymity of the participants in accordance with current legislation and previously described in this document.

The research staff has signed the commitment to act in accordance with the good research practices contained in the Declaration of Helsinki and its updates (the last one signed in Fortaleza, Brazil 2013).

What if you decide to retire from the studio?

You have the right to withdraw your consent to the processing of your data at any time and without having to give any explanation, by requesting the waiver form from any professional in the team, or by calling the CAP II Mataró-Maresme, telephone 93 741 51 77 (Carme Sánchez). You also have the right to file a complaint with the Catalan Data Protection Authority if you consider that any action by the data controller violates your rights.

What if you have doubts about the project or about your participation?

You can contact us through the email of the principal investigator of this project (Carme Sánchez): csanchezm.ics@gencat.cat, or by calling the Rehabilitation Service of the CAP II Mataró-Maresme (93 741 51 77).

Thank you very much for participating.

Name of the project collaborator (representing the research team) who delivers the document and informs the participant: ..... The research team responsible for the study is the one who has informed him about the different aspects of the study. If you wish to ask any questions about the information presented or if you want some clarification of any doubts about the study, you can express it at any time. If you decide to participate in this study, you must give your consent freely. The promoters of the study and the principal investigator are grateful for their invaluable collaboration.

Signed: .....

Name and surname of the participant:

D.N.I.: Age: Data:

PATIENT INFORMATION SHEET (HIP)

Name of the candidate to participate in the study:

Within the framework of a PhD project by the Doctoral School of the University of Vic - Central University of Catalonia (UVIC-UCC), the physiotherapist Carme Sánchez Mato, as a PhD student, promoter of the study and principal investigator, carries out the research project with the title: "**Effectiveness of a combined therapy of the Super Inductive System (SIS) with a therapeutic exercise program of physiotherapy and health education in the lateral elbow tendinopathies".**

Objectives of the study

The main objective of this study, for which we are asking for your collaboration, is to evaluate the effectiveness of SIS in cases of lateral elbow tendinopathies in people aged 18 years or older. The application of the SIS will be combined with an exercise and health education program, to reduce pain, improve the mobility and functionality of the upper extremity, increase grip strength and evaluate the quality of life of those who suffer from this problem.

With this document we provide you with information and invite you to participate in the study. You can ask any questions and request more information on any aspect that you do not understand. Do not approve and sign this document until you are satisfied with the answers to your questions.

The completion of this study has received the approval of the Research Ethics Committee of IDIAP Jordi Gol, which is responsible for ensuring the protection of the rights of the participants and that the methodology of the study is correct.

Why is this study being conducted?

Epicondylalgia is a musculoskeletal disorder that causes pain and dysfunction in the upper extremity. It is related to repetitive movements of the elbow and hand, during sports and work or domestic activities, which require intense force in inappropriate postures, causing limitations in daily work and activities of daily living. It is therefore a major public health problem.

The symptoms that occur with epicondylalgia are pain in the area of insertion of the muscles that are inserted in the elbow, impairment of strength, functionality and quality of life.

SIS is an innovative and non-invasive therapeutic technology. It reduces acute and chronic pain, improves joint mobility and muscle strengthening, among others. Its implementation could accelerate recovery from this pathology. The aim is to obtain evidence on its effectiveness and cost-efficiency, contributing to the reduction of the time of incapacity for work, treatment and recovery time, as well as expenditure on pharmacological treatment.

What does the study consist of and what is expected of you as a participant?

To be part of the study, participants will need to answer questions asked by the evaluators and then a series of questionnaires with specific questions about the aspects to be evaluated. Then, they must go for treatment for 8 days, and they will be evaluated again using the same questionnaires. Three and six months after finishing the program, he will be summoned again to answer these last questionnaires, again to see how he has evolved. The first visit will last approximately 45 minutes, the rest will last no more than 20 minutes. Treatment sessions last approximately 45 minutes.

This study involves a sample of users from three different Rehabilitation and Physiotherapy Services (Vallès, Sant Andreu de Barcelona and Astilleros de Barcelona), referred by the Family Doctor, Traumatologist, Rheumatologist or Rehabilitation Doctor or by the Traumatologist. The administrative staff has contacted you to make an appointment with the physiotherapist who will perform the evaluation. On this visit you will be given detailed information and invited to participate in the research study.

Users will be divided into two groups. In one of them, an exercise program will be carried out to improve the mobility and strength of the muscles of the affected upper extremity. They will be given a sheet with recommendations (health education) on the pathology and the SIS will be applied, with the pre-established program for tendinopathies and with an intensity according to the motor threshold of each patient. The other group will carry out the same exercise and health education program, but the SIS will be applied with non-therapeutic doses. Randomly, they will assign it to one group or another.

In both groups, a total of 8 sessions will be held, with a frequency of two days a week. The days that he does not attend rehabilitation he will have to do them at home. It will not take more than 20 minutes a day.

If you have been included in the group in which the application of SIS parameters is not therapeutic and the results of the study are beneficial, please note that in the future you could benefit from this project. The participants in this group will not stop obtaining the conventional treatment that, until now, has been applied to tendinopathies; that is, the exercise program and health education.

Your participation in this research study is entirely voluntary. If during the development of the study you decide to withdraw, you can do so freely at any time you consider appropriate, without any need to give explanations and without altering your relationship with the researchers and collaborators of the study.

Who can participate in the study?

All those adults who have pain in the external lateral area of the elbow, referred by the family doctor, traumatologist, rheumatologist or rehabilitation doctor, can participate in the project. Reasons for exclusion from the study will be those people who have had a recent traumatic history (less than 6 months), who have a limitation of passive mobility of the elbow, and have received infiltration in the affected elbow in the last 6 weeks, are carriers of pacemakers or metal implants in the affected area, have cognitive or sensory difficulty that prevents their participation in the proposed treatment or suffer from some other condition that their doctor or evaluator considers a difficulty for their participation.

What if I decided to participate in the study?

You should know that your participation in this study is voluntary and that you can choose not to participate. You can change your decision and withdraw your consent at any time without altering your relationship with the doctor or physiotherapist or causing any prejudice to your care. If you decide to participate, with your signature you would be accepting that the care team and researcher in charge can analyze your clinical history with the sole purpose of knowing what your current clinical situation is and what your evolution is during the follow-up of this study. With your participation, you will help the scientific community to better understand the influence of SIS on lateral elbow tendinopathies in order to be able to address them excellently in the future. For his part, he will receive the current treatment established by protocol for the management of his ailment.

Data confidentiality

The results of the various tests carried out, as well as the documentation relating to him, are absolutely confidential and will only be available to the research team and the competent health authorities, where appropriate.

Publication of the results

The research team recognizes the importance and significance of the study and, therefore, is willing to publish the results in a journal, publication or scientific meeting to be determined. If you wish, the researcher responsible for the study will inform you of the results, as well as any other relevant data that is known during the study.

Information on confidentiality and data protection. How will your personal data be processed?

All participants will be assigned a code by which it is impossible to identify the participant with the answers given, fully guaranteeing confidentiality under the responsibility of the Catalan Institute of Health as data controller (hereinafter the "data controller").

The data that will be obtained through their participation will not be used for any purpose other than that explained in this research and will become part of a data file for which the principal investigator will be the maximum responsible.

This data will be collected, stored and protected through the use of the REDCap Web application. Only the researchers of the study will be able to access them.

The processing of the data will be carried out in compliance with the "Regulation (EU) 2016/679 of the European Parliament and of the Council", of 27 April 2016, on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (GDPR), and the "Organic Law 3/2018, on Data Protection and guarantee of digital rights". (LOPD-GDD).

In accordance with this law, you may exceed the rights of access, modification, opposition and cancellation of this data by contacting the Data Protection Officer (dpd@ticsalutsocial.cat) or by contacting Carme Sánchez, at CAP II Maresme, on 93 741 51 77, principal investigator of this project.

By signing this document, you expressly consent to your data being processed for research purposes within the framework of this project, in accordance with article 6.1.a, 9.2.a of the GDPR. This data will be kept for 5 years after the completion and communication of the completion of the project. Communications of personal data are not contemplated, beyond those provided for by law. No international data transfers will be made either.

The publication and dissemination of the research results of the project will be carried out scrupulously respecting the anonymity of the participants in accordance with the legislation in force and described in this document previously.

The researchers have signed the commitment to act in accordance with the good research practices set out in the Declaration of Helsinki and its updates (the last one signed in Fortaleza, Brazil 2013).

What if you decide to withdraw from the study?

You have the right to withdraw your consent to the processing of the data at any time and without having to give any explanation, by requesting the resignation form from any professional in the team, or by calling CAP II Mataró-Vallès, telephone 93 741 51 77 (Carme Sánchez). You also have the

right to file a complaint with the Catalan Data Protection Authority if you consider that any action by the data controller violates your rights.

What if you have questions about the project or your participation?

You can contact us through the email of the principal investigator of this project (Carme Sánchez): csanchezm.ics@gencat.cat, or by calling the Rehabilitation Service of CAP II Mataró-Vallès (93 741 51 77).

Thank you very much for participating.

Name of the project collaborator (representing the research team) who delivers the document and informs the participant: ..... The research team responsible for the study has informed you about the different aspects of the study. If you have any questions about the information on display or if you would like clarification of any doubts about the study, you may ask them at any time. If you decide to participate in this study, you will be free to give your consent. The promoters of the study and the principal investigator are grateful for their invaluable collaboration.

Signed: .....

Name and surname of the participant:

D.N.I.: Age: Date:

ANNEX 2: INFORMED CONSENT

INFORMED CONSENT (CI)

Title of the study: Effectiveness of a combined therapy of the Super Inductive System (SIS) with a therapeutic exercise program of physiotherapy and health education in lateral tendinopathies of the elbow.

I (Name and surname),....., with D.N.I. nº ....., over 18 years of age, acting in my own name and interest, declare that I have been informed in a clear, broad and satisfactory way, orally and I have read the information sheet to the participant that has been given to me.

I have had the opportunity to ask all the questions I wanted about the study. I have received enough information about the study. I spoke to ....., who gave me the information and a copy of the consent. I understand that my participation is voluntary.

I understand that I can withdraw from the study:

1. whenever you want,

2. without giving explanations, and

3. without this having an impact on the medical or physiotherapy care they receive.

In accordance with the provisions of Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April on Data Protection (GDPR) and Organic Law 3/2018, of 5 December, on Data Protection and Guarantee of Digital Rights, I declare that I have been informed of my rights, the purpose for which my data was collected and the recipients of the information. I freely consent to participate in this study.

I GIVE MY CONSENT TO:

1. To participate in "Effectiveness of a combined therapy of the Super Inductive System (SIS) with a therapeutic exercise program of physiotherapy and health education in lateral elbow tendinopathies".
2. That Carme Sánchez Mato, as principal investigator, can manage my personal data and disseminate the information that the project generates. It is guaranteed that my identity and privacy will be preserved at all times, with the guarantees established in Organic Law 3/2018, of 5 December, on the Protection of Personal Data and guarantee of digital rights and General Regulation (EU) 2016/679, of 27 April 2016, on data protection and complementary regulations.
3. That Carme Sánchez Mato keep all the records made about me in electronic format, with the guarantees and deadlines provided for by law, if they were established, and in the absence of legal provision, for the time necessary to fulfill the functions of the project for which the data were collected.

Name and surname of the participant and signature:

D.N.I.: Age: Data:

Principal Investigator: .....

Signature of the principal investigator:

STATEMENT BY THE RESEARCHER

The patient who signs this consent form has received, from the professional, detailed information, orally and in writing, of the process and nature of this research study, and has had the opportunity to ask any questions regarding the nature, risks and advantages of participating in this study.

Signature of the researcher: Date:

INFORMED CONSENT (CI)

Study title: Effectiveness of a combined therapy of the Super Inductive System (SIS) with a therapeutic exercise program of physiotherapy and health education in lateral elbow tendinopathies.

I (Name and surname),....., with ID No. ....., over 18 years of age, acting in my own name and interest, declare that I have been informed in a clear, comprehensive and satisfactory manner, orally and I have read the information sheet to the participant that has been given to me.

I have had the opportunity to ask all the questions I have wanted about the study. I have received enough information about the study. I have spoken to ....., who has given me the information and a copy of the consent. I understand that my participation is voluntary.

I understand that I can withdraw from the study:

1. when you want,

2. without giving explanations, and

3. without this having an impact on the medical or physiotherapy care they receive.

In accordance with the provisions of Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April on Data Protection (GDPR) and Organic Law 3/2018, of 5 December, on data protection and guarantee of digital rights, I declare that I have been informed of my rights, the purpose of collecting my data and the recipients of the information. I freely consent to participate in this study.

I CONSENT TO:

1. Participate in "Effectiveness of a combined therapy of the Super Inductive System (SIS) with a therapeutic exercise program of physiotherapy and health education in lateral elbow tendinopathies".
2. That Carme Sánchez Mato, as principal investigator, can manage my personal data and disseminate the information that the project generates. It is guaranteed that my identity and privacy will be preserved at all times, with the guarantees established in Organic Law 3/2018, of 5 December, on the Protection of Personal Data and guarantee of digital rights and the General Regulation (EU) 2016 / 679, of 27 April 2016, on data protection and complementary regulations.
3. That Carme Sánchez Mato keep all the records made about me in electronic format, with the guarantees and deadlines provided for by law, if established, and in the absence of legal provision, for the time necessary to fulfil the functions of the project for which the data were collected.

Name and surname of the participant and signature:

D.N.I.: Age: Date:

Principal Investigator: .....

Signature of the principal investigator:

STATEMENT OF THE RESEARCHER

The patient who signs this consent form has received, from the professional, detailed information, orally and in writing, of the process and nature of this research study, and has had the opportunity to ask any questions regarding the nature, risks and advantages of participating in this study.

Signature of the researcher: Date:

ANNEX 3: WAIVER FORM

FULL RESIGNATION

Title of the study: Effectiveness of a combined therapy of the Super Inductive System (SIS) with a therapeutic exercise program of physiotherapy and health education in lateral tendinopathies of the elbow.

I (Name and surname),....., with D.N.I. nº ....., declare that it is my desire to abandon the study in which I have been participating.

I declare that there has been no pressure or insistence on giving my personal reasons for resigning, in accordance with the rules and procedures for inclusion in the study.

I have to talk to (Name of the researcher who has given the information): .....

I understand that my participation was, at all times, voluntary and it is my desire to leave the studio.

I understand that I can withdraw from the study:

1° at the time I wish,

2° without having to give any explanation, and

3° without this fact having an impact on my relationship with the researchers or promoters of the study.

In conclusion, I renounce to continue participating in this study.

Principal Investigator: .....

Signature of the principal investigator:

Data:

WAIVER SHEET

Study title: Effectiveness of a combined therapy of the Super Inductive System (SIS) with a therapeutic exercise program of physiotherapy and health education in lateral elbow tendinopathies.

I (Name and surname),....., with ID No. ....., declare that it is my wish to leave the studio in which I have been participating.

I declare that there has been no pressure or insistence on giving my personal reasons for resigning, in accordance with the rules and procedures for inclusion in the study.

I have spoken to (Name of the researcher who gave the information): .....

I understand that my participation was, at all times, voluntary and it is my desire to leave the studio.

I understand that I can withdraw from the study:

1° at the time I wish,

2° without having to give any explanation, and

3° without this fact having an impact on my relationship with the researchers or promoters of the study.

In conclusion, I renounce to continue participating in this study.

Principal Investigator: .....

Signature of the principal investigator:

Date:

ANNEX 4: DATA COLLECTION SHEET

DATA COLLECTION SHEET

Date: **Identifier:**

Sociodemographic data:

Origin of the referral (Family Doctor/Traumatologist/Rehabilitation Doctor):

Reference Primary Care Centre:

Center where the intervention will be carried out (Mataró/Sant Andreu/Drassanes Rehabilitation Service):

Age: Gender: Affected limb: Dominant Hand:

Medical diagnosis: Time of pain evolution:

Health History:

Previous traumatic history? (date): Surgical intervention on the affected elbow? (date):

Infiltration? (date):

Educational level:

Marital status: Coexistence:

Employment:

Physical and sports activity: YES/NO Type: Dedication time:

Pain (rhythm and characteristics):

Type: Without/with irradiation: Duration: Aggravation: Evolution time:

Daytime / Night:

EVA at rest (average of the last week):

Mechanical EVA (average of the last week):

Current pain-related pharmacological treatment/dosage:

Use of orthosis for the affected elbow: YES/NO Time of use:

Situation of temporary disability due to the reason for the study: Start date: Duration:

Diagnostic tests performed (X-ray, ultrasound, MRI)/date of performance:

Previous treatments (Rehabilitation, infiltrations, private physiotherapy,...):

Exploration:

Joint balance:

Cozen maneuver (resisted carpal extension / chair test):

Miller maneuver:

Palpation:

Epicondyle-common extensor tendon:

Radiohumeral joint:

Trigger points (triceps, anconium, brachiradial, extensor carpi radial, extensor fingers):

NOTE:

- Reasons for exclusion from the study: Medial epicondyalgia of the elbow, recent traumatic history (<6 months), limitation in passive joint mobility (elbow fracture, surgery), infiltration in the affected elbow (6 weeks prior to the first visit), pain due to inflammatory, autoimmune or infectious systemic disease, pregnant women, metastatic disease, metal implants in the affected elbow area, pacemakers, Frohse's arch syndrome, blood clotting disorders.
- In the event of involvement of both elbows, priority will be given to treating only one, as part of the study. In the event that you subsequently need to receive treatment for the other elbow, this second process will no longer be part of the study.

Main variable:

Pain:

EVA

Previous	Post-intervention	Control 3 months	Control 6 months

Algometry

Previous	Post-intervention	Control 3 months	Control 6 months

Gonometry (joint mobility):

	Previous	Post-intervention	Control 3 months	Control 6 months
Elbow flexion				
Elbow extension				
Elbow pronation				
Elbow supination				
Elbow affection flexion				
Elbow Affect Extension				
Elbow affection pronation				
Elbow affect, supination				

Dynamometry (gripping force):

Previous	Post-intervention	Control 3 months	Control 6 months

Functionality (QuickDASH):

Previous	Post-intervention	Control 3 months	Control 6 months

Quality of Life (EQ-5D-5L):

Previous	Post-intervention	Control 3 months	Control 6 months

Number of treatment sessions performed:

Adherence to treatment: % (of the total number of days per week, how many have exercised).

Adverse effects: (included in the adverse effects collection sheet)

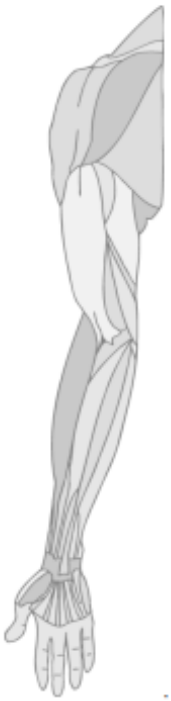
He believes that he has been applied the SIS program for epicondylitis or the SIS with a non-therapeutic dose: (blinding assessment)

ANNEX 5: ASSESSMENT SCALES

- **QUICKDASH:**

*Quick*DASH
Versión Española (España)

Instrucciones



Este cuestionario le pregunta sobre sus síntomas así como su capacidad para realizar ciertas actividades o tareas
Por favor conteste cada pregunta basándose en su condición o capacidad durante la última semana. Para ello marque un círculo en el número apropiado.

Si usted no tuvo la oportunidad de realizar alguna de las actividades durante la última semana, por favor intente aproximarse a la respuesta que considere que sea la más exacta.

No importa que mano o brazo use para realizar la actividad; por favor conteste basándose en su habilidad o capacidad y como puede llevar a cabo dicha tarea o actividad

Spanish (Spain) translation courtesy of Dr. R.S. Rosales, MD, PhD, Institute for Research in Hand Surgery, GECOT, Unidad de Cirugía de La Mano y Microcirugía, Tenerife, Spain

Por favor, puntúe su habilidad o capacidad para realizar las siguientes actividades durante la última semana. Para ello, marque con un círculo el número apropiado para cada respuesta.

	Ninguna dificultad	Dificultad leve	Dificultad moderada	Mucha dificultad	Imposible de realizar
1. -Abrir un bote de cristal nuevo	1	2	3	4	5
2.-Realizar tareas duras de la casa (p. ej. fregar el piso, limpiar paredes, etc.	1	2	3	4	5
3.-Cargar una bolsa del supermercado o un maletin.	1	2	3	4	5
4.-Lavarse la espalda	1	2	3	4	5
5.-Usar un cuchillo para cortar la comida	1	2	3	4	5
6.-Actividades de entretenimiento que requieren algo de esfuerzo o impacto para su brazo, hombro o mano (p. ej. golf, martillear, tenis o petanca)	1	2	3	4	5
	No, para nada	Un poco	Regular	Bastante	Mucho
7.- Durante la última semana, ¿ su problema en el hombro, brazo o mano ha interferido con sus actividades sociales normales con la familia, sus amigos, vecinos o grupos?	1	2	3	4	5

	No para nada	Un poco	Regular	Bastante limitado	Imposible de realizar
8.- Durante la última semana, ¿ha tenido usted dificultad para realizar su trabajo u otras actividades cotidianas debido a su problema en el brazo, hombro o mano?	1	2	3	4	5

Por favor, ponga puntuación a la gravedad o severidad de los siguientes síntomas	Ninguno	Leve	Moderado	Grave	Muy grave
9.- Dolor en el brazo, hombro o mano.	1	2	3	4	5
10.-Sensación de calambres (hormigueos y alfilerazos) en su brazo hombro o mano.	1	2	3	4	5

	No	Leve	Moderada	Grave	Dificultad extrema que me impedía dormir
11.- Durante la última semana, ¿cuanta dificultad ha tenido para dormir debido a dolor en el brazo, hombro o mano?.	1	2	3	4	5

Cálculo de la puntuación del "Quick Dash" (Discapacidad/Síntomas) = ([(suma de n respuestas)/n] -1) x 25, donde n es igual al número de respuestas completadas. La puntuación del "Quick Dash" no puede ser calculada si hay más de 1 ítem sin contestar.

Módulo de Trabajo (Opcional)

Las siguientes preguntas se refieren al impacto que tiene su problema del brazo, hombro o mano en su capacidad para trabajar (incluyendo las tareas de la casa si ese es su trabajo principal)

Por favor, indique cuál es su trabajo/ocupación: _____

Yo no trabajo (usted puede pasar por alto esta sección) .

Marque con un círculo el número que describa mejor su capacidad física en la semana pasada. **¿Tuvo usted alguna dificultad...**

	Ninguna dificultad	Dificultad leve	Dificultad moderada	Mucha dificultad	Imposible de realizar
1. para usar su técnica habitual en su trabajo?	**1**	**2**	**3**	**4**	**5**
2. para hacer su trabajo habitual debido al dolor del hombro, brazo o mano?	**1**	**2**	**3**	**4**	**5**
3. para realizar su trabajo tan bien como le gustaría?	**1**	**2**	**3**	**4**	**5**
4. para emplear la cantidad habitual de tiempo en su trabajo?	**1**	**2**	**3**	**4**	**5**

Actividades especiales deportes/músicos (Opcional)

Las preguntas siguientes hacen referencia al impacto que tiene su problema en el brazo, hombro o mano para tocar su instrumento musical, practicar su deporte, o ambos. Si usted practica más de un deporte o toca más de un instrumento (o hace ambas cosas), por favor conteste con respecto a la actividad que sea más importante para usted. Por favor, indique el deporte o instrumento que sea más importante para usted.

Marque con un círculo el número que describa mejor su capacidad física en la semana pasada
¿Tuvo alguna dificultad.:

	Ninguna dificultad	Dificultad leve	Dificultad moderada	Mucha dificultad	Imposible de realizar
para usar su técnica habitual al tocar su instrumento o practicar su deporte?	1	2	3	4	5
para tocar su instrumento habitual o practicar su deporte debido a dolor en el brazo, hombro o mano ?	1	2	3	4	5
para tocar su instrumento o practicar su deporte tan bien como le gustaría?	1	2	3	4	5
para emplear la cantidad de tiempo habitual en tocar su instrumento o practicar su deporte?	1	2	3	4	5

Puntuación de los Módulos Opcionales: Sumar los valores asignados a cada respuesta en cada módulo; divídalo por 4 (número de ítems en cada módulo); restar 1; multiplique por 25.. La puntuación de un módulo opcional no puede ser calculada si hay algún ítem sin contestar.

- **EQ-5D-5L:**

Identifier **Date:**

Debajo de cada enunciado, marque UNA casilla, la que mejor describe su salud HOY.

MOVILIDAD

No tengo problemas para caminar ❑
Tengo problemas leves para caminar ❑
Tengo problemas moderados para caminar ❑
Tengo problemas graves para caminar ❑
No puedo caminar ❑

AUTO-CUIDADO

No tengo problemas para lavarme o vestirme ❑
Tengo problemas leves para lavarme o vestirme ❑
Tengo problemas moderados para lavarme o vestirme ❑
Tengo problemas graves para lavarme o vestirme ❑
No puedo lavarme o vestirme ❑

ACTIVIDADES COTIDIANAS *(Ej.: trabajar, estudiar, hacer las tareas domésticas, actividades familiares o actividades durante el tiempo libre)*

No tengo problemas para realizar mis actividades cotidianas ❑
Tengo problemas leves para realizar mis actividades cotidianas ❑
Tengo problemas moderados para realizar mis actividades cotidianas ❑
Tengo problemas graves para realizar mis actividades cotidianas ❑
No puedo realizar mis actividades cotidianas ❑

DOLOR / MALESTAR

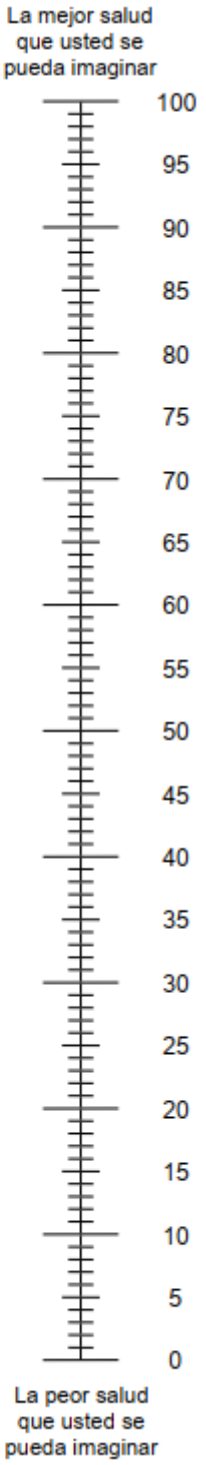
No tengo dolor ni malestar ❑
Tengo dolor o malestar leve ❑
Tengo dolor o malestar moderado ❑
Tengo dolor o malestar fuerte ❑
Tengo dolor o malestar extremo ❑

ANSIEDAD / DEPRESIÓN

No estoy ansioso ni deprimido ❑
Estoy levemente ansioso o deprimido ❑
Estoy moderadamente ansioso o deprimido ❑
Estoy muy ansioso o deprimido ❑
Estoy extremadamente ansioso o deprimido ❑

- Nos gustaría conocer lo buena o mala que es su salud HOY.
- La escala está numerada del 0 al 100.
- 100 representa la mejor salud que usted se pueda imaginar. 0 representa la peor salud que usted se pueda imaginar.
- Marque con una X en la escala para indicar cuál es su estado de salud HOY.
- Ahora, en la casilla que encontrará a continuación escriba el número que ha marcado en la escala.

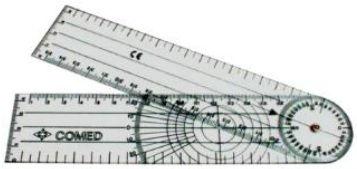
SU SALUD HOY = ☐



ANNEX 6: MEASURING INSTRUMENTS

- **EVA:**

- **Goniometer:**



- **Manual pressure algometer (PAIN TEST TM FPX 50):**

- **JAMAR Hydraulic Hand Dynamometer:**

ANNEX 7: THERAPEUTIC EXERCISE PROTOCOL FOR LATERAL ELBOW TENDINOPATHY

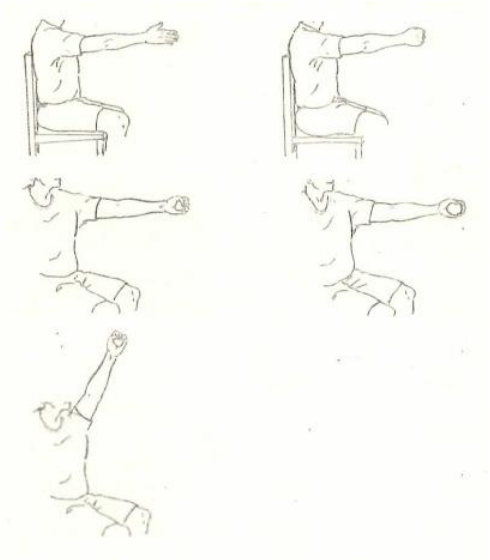
Recommendations for carrying out the exercises / Recommendations for carrying out the exercises:

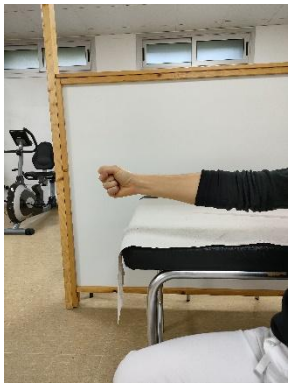
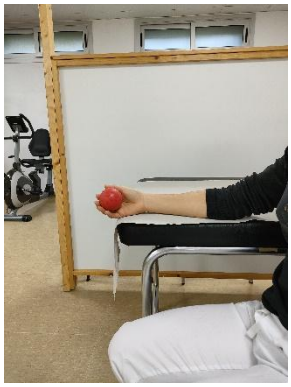
- Frequency of performance: 4 days a week. / Frequency of performance: 4 days per week.
- Repetitions: 2 sets of 10 repetitions. / Reps: 2 sets of 10 reps.
- Objective: to work on mobility, strength, endurance and functionality. / Objective: to work on mobility, strength, endurance and functionality.
- On the days that you attend physiotherapy (two days a week), you can take the opportunity to perform the exercises at the center and the rest of the days, you will have to do them at home. / The days you attend physiotherapy (two days a week), you can take advantage of it to perform the exercises at the center and the rest of the days, you must do them at home.
- Progression criteria:
    - Increase/decrease the load of exercises with weight, repetitions, joint range or speed depending on the pain presented or the ease of execution. / Increase/decrease the load of exercises with weight, repetitions, joint range or speed depending on the pain you present or the ease of execution.
    - If there is no increase in pain during the 24 hours after performing the exercises. / If there is no increase in pain during the 24 hours after performing the exercises.
- Cannot exceed an EVA of 5 during the performance of the exercises (feeling of discomfort but not intense pain) / Cannot exceed an EVA of 5 during the performance of the exercises (feeling of discomfort but not intense pain).
- One day a week the physiotherapist will carry out an assessment to decide on the progression of the exercises. / One day a week the physiotherapist will carry out an assessment to decide on the progression of the exercises.

1- Simple Grip & Counter-Resistance / Simple & Counter-Resistance Grip:

PROGRESSION OF EXERCISES/PROGRESSION OF EXERCISES:

A) FIRST WEEK / FIRST WEEK: close your hand for 5 seconds and open it / close your hand for 5 seconds and open it.
B) SEGONA SETMANA / SECOND WEEK: to hold the most 5 seconds prement a pilot and relax / close the hand for 5 seconds, squeezing a ball and relaxing.
C) THIRD WEEK / THIRD WEEK: throwing the ball against the ground and catching it / throwing

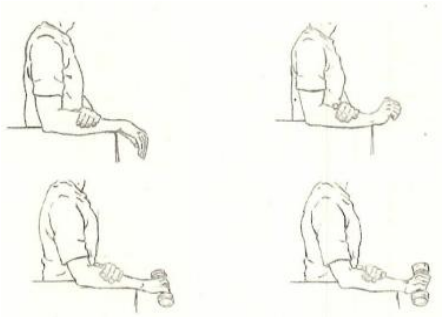


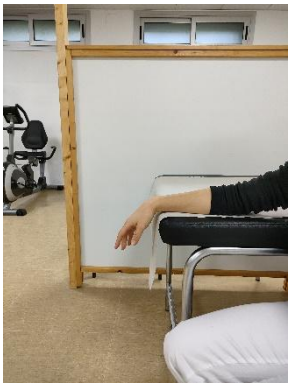




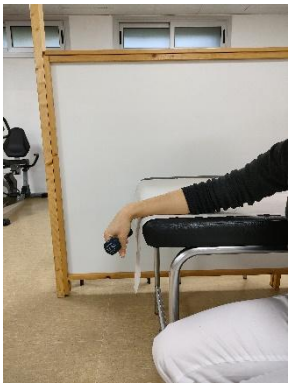
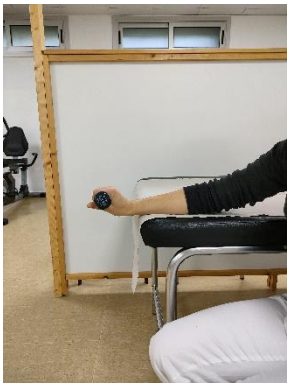
2- Wrist extension without and with weight / Wrist extension without and with weight:

PROGRESSION OF EXERCISES/PROGRESSION OF EXERCISES:

A) FIRST WEEK / FIRST WEEK: hold wrist extension by resisting with the opposite hand, for 5 seconds and relax / hold wrist extension by resisting with the opposite hand, for 5 seconds and relax.
B) SEGUNDA SEMANA / SEGUNDA SEMANA: wrist extension with weight (1/2 liter bottle) for 5 seconds and relax / wrist extension with weight (1/2 liter bottle) for 5 seconds and relax.
C) THIRD WEEK / THIRD WEEK: wrist extension with weight (1 liter bottle) for 5 seconds and relax / wrist extension with weight (1 liter bottle) for 5 seconds and relax.



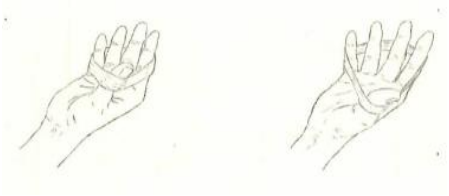


3- Opening and extension of fingers against resistance / Opening and extension of fingers against resistance:

PROGRESSION OF EXERCISES/PROGRESSION OF EXERCISES:

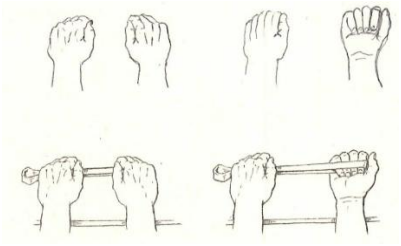
FIRST WEEK / FIRST WEEK: to separate fingers from the hand against the resistance of an eraser / to separate fingers from the hand using the resistance of an eraser.
SEGUNDA SEMANA / SEGUNDA SEMANA: separate fingers of the hand against the resistance of two erasers / separate fingers of the hand using the resistance of two erasers.

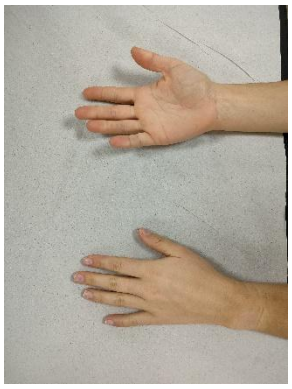


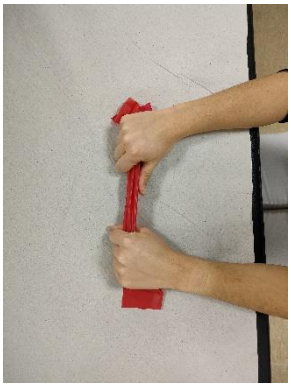
4- Supination without and with elastic band / Supination without and with elastic band:

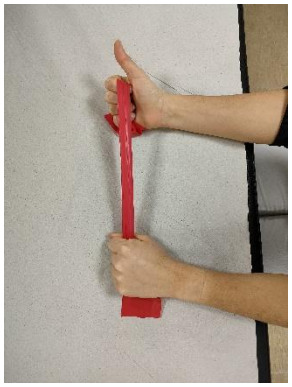
PROGRESSION OF EXERCISES/PROGRESSION OF EXERCISES:

A) PRIMERA SEMANA / PRIMERA SEMANA: starting from the pronation, go towards the supination with the hand on the table (palm of the hand up and down) / starting from the pronation, go towards the supination with the hand on the table (palm of the hand up and down).
B) SEGUNDA SEMANA / SEGUNDA SEMANA: use a glove or rubber band to turn the palm upwards / use a glove or rubber band to turn the palm of the hand upwards.
C) THIRD WEEK / THIRD WEEK: use double glove / use double glove.





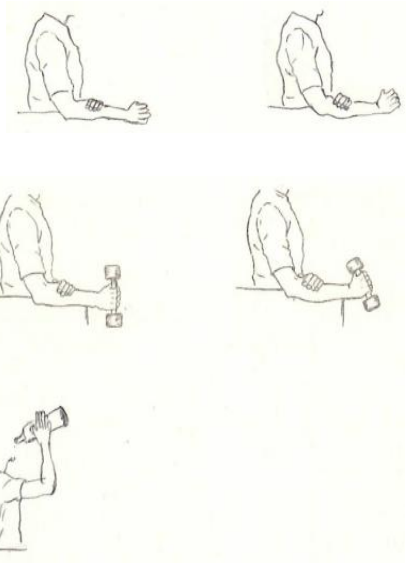


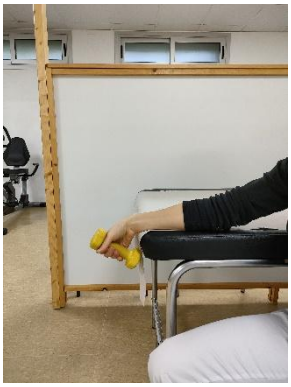


5- Radial deviation without and with weight. Functionality / Radial deviation without and with weight. Functionality:

PROGRESSION OF EXERCISES/PROGRESSION OF EXERCISES:

A) FIRST WEEK / FIRST WEEK: place the arm in a neutral position with the thumb facing the ceiling. Raise and lower your thumb. / Place your arm in a neutral position with your thumb facing the ceiling. Raise and lower your thumb.
B) SEGUNDA SEMANA / SEGUNDA SEMANA: same previous exercise using a half liter bottle / mismo ejercicio anterior usando una botella de medio litro.
C) THIRD WEEK / THIRD WEEK: fer com si estigués bevent aigua d'una ampolla de litre i mig / to make as if he were drinking water from a liter and a half bottle.

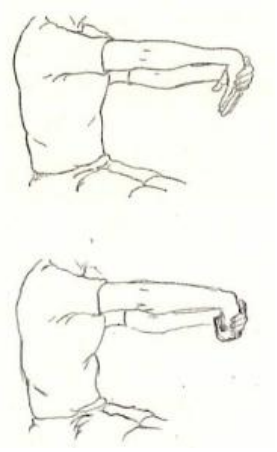





6- Epicondylia musculature stretching / Epicondylar musculature stretching:

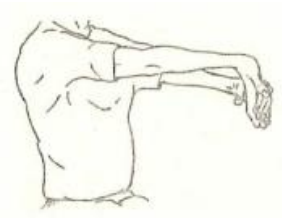
PROGRESSION OF EXERCISES/PROGRESSION OF EXERCISES:

A) FIRST WEEK / FIRST WEEK: flex the wrist with the open fist. Hold the position for 15 seconds / bend the wrist with the fist open. Hold the position for 15 seconds.
B) SEGUNDA SEMANA / SEGUNDA SEMANA: flex the wrist with the fist closed. Hold the position for 15 seconds / bend the wrist with the fist closed. Hold the position for 5 seconds.



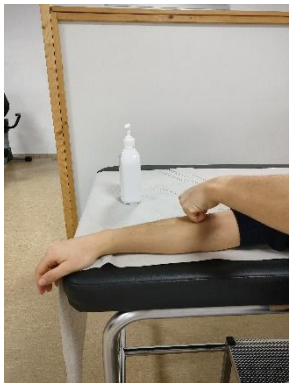
7- Epitrochlear muscle stretching / Epitrochlear muscle stretching:

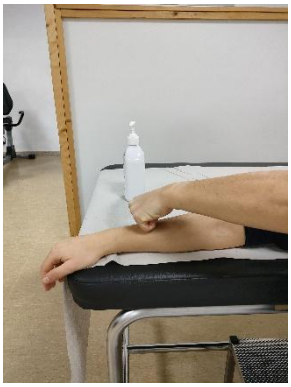
PROGRESSION OF EXERCISES/PROGRESSION OF EXERCISES: Extend the wrist with the fist open. Hold the position for 15 seconds / Extend the wrist with the fist open.



8- Self-massage of the epicondylar muscles / Self-massage of the epicondylar muscles:

PROGRESSION OF EXERCISES/PROGRESSION OF EXERCISES: SELF-MASSAGE: perform self-massage of the forearm muscles (between elbow and wrist), gently, between 2 and 5 minutes / perform self-massage of the forearm muscles (between elbow and wrist), gently, between 3 and 5 minutes.





ANNEX 8: HEALTH EDUCATION SHEET. RECOMMENDATIONS

HEALTH INFORMATION SHEET: EPICONDYLITIS

What is tennis player's epincondylitis or elbow?

Tennis elbow epicondylitis is characterized by pain on the outside of the elbow, where the tendons of the extensor muscles of the wrist are inserted. It is an injury frequently related to repetitive movements of the elbow and hand, during sports and work or domestic activities, which require intense force in inappropriate postures.

It is *manifested* by pain and sensitivity on the outside of the elbow accompanied by a lack of claw strength and the functionality of the upper limb that makes it difficult to perform usual tasks such as lifting a glass, shaking hands, holding a tool, getting dressed... It affects, therefore, the quality of life of the individual.

In order to manage pain, improve strength and recover previous function, in addition to rehabilitative treatment, health education and modification of activity are recommended.

It can be prevented by trying to avoid forced and repetitive movements:

- Repetitive movements with the elbow in extension with or without resistance.
- Forced wrist movements.
- Prolonged periods keeping the arms elevated.
- Handling of heavy loads >20 Kg plus 10 times a day.
- Repetitive movements for more than 2 hours a day.

Therefore, it is recommended:

- Avoid fast, repetitive and forced movements.
- Avoid static and uncomfortable/immobile positions:
    - Elbow at 90º.
    - Arms attached to the body.

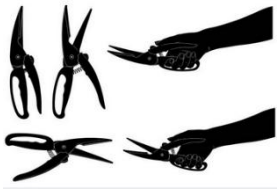
- Wrist in neutral position.



- Use both hands to pick up weights.

- Use light utensils and wide, ergonomic handles.
- Alternate periods of activity and rest.

- Encourage the change of tasks or modify those that cause pain.
- Use adaptations or support products to carry out daily tasks.

Bibliographic reference:

- **UPTODATE. AUTHOR:** Neeru Jayanthi, MD **SECTION EDITOR:** Karl B Fields, MD **DEPUTY EDITOR** Jonathan S Grayzel, MD. Contributor Disclosures. All topics are updated as new evidence becomes available and ourpeer review processis complete. Literature review current through:**Jan 2025.** This topic last updated:**Oct 11, 2024.**
- Tran T, Falkmer T, Ciccarelli M. Do hand therapists have a role in workplace-based education to manage tennis elbow? Beliefs about effective treatments among Australian hand therapists and medical practitioners. Work. 2020; 66(3):539-549. doi: 10.3233/WOR-203196. PMID: 32623416.
- Images: https://www.istockphoto.com/

HEALTH INFORMATION SHEET: EPICONDYLITIS

What is epincondylitis or tennis elbow?

Epicondylitis or tennis elbow is characterized by pain on the outside of the elbow, where the tendons of the wrist extensor muscles are inserted. It is an injury frequently related to repetitive movements of the elbow and hand, during sports and work or domestic activities, which require intense force in inappropriate postures.

It is *manifested* by pain and sensitivity to the outside of the elbow accompanied by a lack of claw strength and functionality of the upper limb that makes it difficult to perform usual tasks such as lifting a glass, shaking hands, holding a tool, getting dressed... It therefore affects the quality of life of the individual.

For pain management, improvement of strength and recovery of previous function, in addition to rehabilitation treatment, health education and activity modification are recommended.

It can be prevented by trying to avoid forced and repetitive movements:

- Repetitive movements with the elbow in extension with or without resistance.
- Forced wrist movements.
- Prolonged periods of keeping your arms elevated.
- Handling of heavy loads >20 kg, more than 10 times a day.
- Repetitive movements for more than 2 hours a day.

Therefore, it is recommended:

- Avoid fast, repetitive and forced movements.
- Avoid static and uncomfortable/immobile positions:
  - the Codo at 90º.
  - o Arms close to the body.
  - o Wrist in neutral position.



o Use both hands to pick up weights.

- Use light utensils and wide, ergonomic handles.
- Alternate periods of activity and rest.

- Encourage the change of tasks or modify those that cause pain.
- Use adaptations or support products to carry out daily activities.




ANNEX 9: RECORD OF EXERCISES CARRIED OUT

Record of exercises carried out

DATA	Exercises carried out	Dedication time	Comments

ANNEX 10: SUPER INDUCTIVE SYSTEM MANUAL

The BTL Super Inductive System (SIS) can be consulted at the following link:

https://www.fisioterapia-madrid.com/btl-6000-sistema-super-inductivo/

"BTL–6000 SUPER INDUCTIVE SYSTEM: What is it, how does it work and what is it used for?

The Super Inductive System (SSI) is an innovative technology that uses high-intensity electromagnetic fields to stimulate biological tissues. The BTL-6000 is a medical device that applies this technology for therapeutic and rehabilitation purposes.

What is the super inductive system?

The super-inductive system is a non-invasive method that generates a high-frequency, high-intensity pulsed electromagnetic field. This field penetrates the human body and produces an electric current in the cells, causing a number of beneficial physiological effects.

How does the super inductive system work?

The super-inductive system is based on the principle of electromagnetic induction, which consists of generating an electric current in a conductor when it is exposed to a variable magnetic field. The BTL-6000 uses a special coil that creates a pulsed magnetic field of up to 2.5 Tesla, which is equivalent to 50,000 times the Earth's magnetic field.

The magnetic field generated by the coil induces an electric current in biological tissues, especially muscles, nerves, and bones. This current stimulates cell activity, improves blood circulation, reduces inflammation, relieves pain and promotes tissue regeneration.

What is the super inductive system used for?

The super-inductive system has multiple clinical applications, both in the field of sports medicine and in neurological and orthopaedic rehabilitation.

Some of the most common indications are:

- Treatment of chronic and acute pain of musculoskeletal origin, such as lumbar, cervical, joint or myofascial pain.
- Functional recovery from muscle, tendon, ligamentous or joint injuries, such as sprains, strains, fibrillar ruptures or osteoarthritis.
- Prevention and treatment of muscle atrophy due to disuse or nerve injury.
- Muscle strengthening and improvement of sports performance.
- Stimulation of bone healing in fractures or pseudoarthrosis.
- Stimulation of the healing of wounds and skin ulcers.

The super inductive system is a safe, effective and comfortable therapy for the patient, as it does not require any direct contact with the skin or cause any undesirable side effects. The BTL-6000 allows the treatment parameters to be adjusted according to the needs and tolerance of each person, offering fast and long-lasting results."

ANNEX 11: CE MARKING OF THE SIS

BTL Industries

EC DECLARATION OF CONFORMITY

Issued according to Annex II
to the Directive 93/42/EEC on Medical devices
as amended by the Directive 2007/47/EC

Manufacturer:	Authorised Representative:
BTL Industries Limited 161 Cleveland Way Stevenage SG1 6BU, Hertfordshire United Kingdom	**BTL ITALIA S.r.l.** Via San Leonardo 120 84131, Salerno Italy

The **BTL Industries Limited** herewith declares under its sole responsibility that the product

Product Description	**High Intensity Magnet**
Product Name:	**BTL-6000 Super Inductive System**
Product Model:	**BTL-6000 Super Inductive System Elite**
Risk Classification:	**Class IIa** According to Annex IX of MDD

is in conformity with requirements of Annex I to the Directive 93/42/EEC on Medical Devices as amended by the Directive 2007/47/EC

and bears the CE mark:	CE 2460
Notified Body:	DNV Product Assurance AS
EC Certificate No.:	10406-2017-CE-CZS-NA-PS

Date of Issue: May 24, 2021
Place of Issue: Stevenage

Signature on behalf of BTL Industries Ltd.

BTL Industries Limited
SG1 6BU Hertfordshire
United Kingdom

Jakub Machalek
Regulatory Affairs Manager

EU Certificate

Quality Management System
REGULATION (EU) 2017/745 on Medical Devices
Annex IX Chapter I, Section 2 and 3 and Chapter III

Registration No.: HZ 2036797-1

Manufacturer: BTL Industries Limited
161 Cleveland Way SG1 6BU Stevenage,
Hertfordshire
United Kingdom

EUDAMED Single Registration No.: GB-MF-000034894

Products: Product of class IIa:
Z129082 - VARIOUS INSTRUMENTS FOR FUNCTIONAL EXPLORATION AND THERAPEUTIC INTERVENTIONS - SOFTWARE ACCESSORIES
Z121501 - SPIROMETRY INSTRUMENTS
Z120503 - ELECTROCARDIOGRAPHS
Z120504 - HOLTER SYSTEM INSTRUMENTS FOR CARDIOVASCULAR PARAMETERS
Z120603 - PASSIVE REHABILITATIVE GYMNASTICS EQUIPMENT
Z120622 - MUSCLE STIMULATORS

The Notified Body hereby declares that the requirements of Annex IX, Chapter I, Section 2 and 3 of the REGULATION (EU) 2017/745 have been met for the listed products. The above named manufacturer has established and applies a quality management system, which is subject to periodic surveillance, defined by Annex IX, Chapter I, Section 3 of the aforementioned regulation. The requirements of Annex IX, Chapter III are fulfilled.
If class III devices or class IIb implantable devices referred to in the second subparagraph of Article 52(4) are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 4.9 is required before placing them on the market.

Report No.: 84968905-20
Effective date: 2024-07-31
Expiry date: 2028-02-02
Issue date: 2024-07-31

Jaroslaw Pyclik
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/745 concerning medical devices with the identification number 0197.

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EU Certificate

Quality Management System
REGULATION (EU) 2017/745 on Medical Devices
Annex IX Chapter I, Section 2 and 3 and Chapter III

Registration No.: HZ 2036797-1

Manufacturer: BTL Industries Limited
161 Cleveland Way
Stevenage, Hertfordshire
SG1 6BU
United Kingdom

EUDAMED Single Registration No.: GB-MF-000034894

Product of class IIb:
Z120690 - VARIOUS PHYSIOTHERAPY AND REHABILITATION INSTRUMENTS
VARIOUS PHYSIOTHERAPY AND REHABILITATION INSTRUMENTS - OTHER

Authorized representative(s): BTL Italia S.R.L
Via San Leonardo 120
84131 Salerno
Italy

Certificate history		
Revision:	Description:	Issue date:
0	Initial certification	2023-02-23
1	Authorised representative changed address, SRN added, Update of expiry date	2024-07-15
2	Scope Extension, Products of class IIa and IIb	2024-07-31

Report No.: 84968905-20
Effective date: 2024-07-31
Expiry date: 2028-02-02
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Business Stream Products
Certification Department

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LGA
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TÜV Rheinland LGA Products GmbH • 51105 Köln

BTL Industries Limited
161 Cleveland Way
Stevenage
Hertfordshire, SG1 6BU
United Kingdom

Contact
Tel. +49 911 655-5225
Mail: [redacted]
Date: June 04, 2024

Notified Body Confirmation Letter
Reference. : PLA_HZ_2024-05-23

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

This letter confirms that **TÜV Rheinland LGA Products GmbH**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **0197** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

BTL Industries Limited
161 Cleveland Way
Stevenage
Hertfordshire, SG1 6BU
United Kingdom
SRN Number (if available): GB-MF-000034894

The devices covered by the formal application and the written agreement mentioned above are identified in the tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after May 26, 2021 but before March 20, 2023 without having been withdrawn, this letter also confirms that the manufacturer either signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by March 20, 2023 for the relevant devices.

TÜV Rheinland
LGA Products GmbH

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Germany

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Nuremberg HRB 28013
VAT No.: DE 811935490

Chairman of the
Supervisory Board

Dr.-Ing. Michael Fibi

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- May 26, 2026 for Class III custom-made implantable devices
- December 31, 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- December 31, 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- December 31, 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body

Digitally signed by Daniel Swiątko
Date: 2024.06.04 08:38:18 +02'00'

Daniel Swiątko
Certification body

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB identification
Exilis; **Exilis Elite** **Basic UDI-DI:** **++B108715PDEEUYZ**	Class IIb non-implantable	Exilis Exilis Elite Exilis Ultra 360	10412-2017-CE-CZS-NA-PS Rev. 4.0; 2460
Exilis Ultra 360 **Basic UDI-DI:** **++B108715PDUEU3L**	Class IIb non-implantable	Exilis Exilis Elite Exilis Ultra 360	10412-2017-CE-CZS-NA-PS Rev. 4.0; 2460
Large applicator 215/1; **XP 2 applicator 215-7;** **XP applicator 215/3** **Basic UDI-DI:** **++B108215APEUUL**	Class IIb non-implantable	Exilis Exilis Elite Exilis Ultra 360	10412-2017-CE-CZS-NA-PS Rev. 4.0; 2460
F tip 215-9; **V tip 215-10;** **V 30 tip 215-11;** **V 24 tip 215-12** **Basic UDI-DI:** **++B108215TIPEUXT**	Class IIb non-implantable	Exilis Exilis Elite Exilis Ultra 360	10412-2017-CE-CZS-NA-PS Rev. 4.0; 2460

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB identification
BTL-6000 Microwave **Basic UDI-DI:** **++B108018PDEUXP**	Class IIb non-implantable	BTL-6000 Microwave BTL-6000 Microwave 250	10407-2017-CE-CZS-NA-PS Rev. 2.0; 2460
Spot radiator BTL-218-1; **Large field radiator BTL-218-2;** **Long radiator BTL-218-3;** **Contact radiator BTL-218-4** **Basic UDI-DI:** **++B108218APEUVM**	Class IIb non-implantable	BTL-6000 Microwave BTL-6000 Microwave 250	10407-2017-CE-CZS-NA-PS Rev. 2.0; 2460
BTL-6000 TR-Therapy Elite; **BTL-6000 TR-Therapy Pro** **Basic UDI-DI:** **++B108049PDEUZ9**	Class IIb non-implantable	BTL-6000 TR-Therapy BTL-6000 TR-Therapy Pro BTL-6000 TR-Therapy Elite	10410-2017-CE-CZS-NA-PS Rev. 2.0; 2460
Capacitive applicator BTL-249-APC1; **Capacitive electrode 20mm BTL-249-C20;** **Capacitive electrode 30mm BTL-249-C30;** **Capacitive electrode 50mm BTL-249-C50;** **Capacitive electrode 70mm BTL-249-C70;** **Resistive applicator BTL-249-APR1;** **Resistive electrode 20mm BTL-249-R20;** **Resistive electrode 30mm BTL-249-R30;** **Resistive electrode 50mm BTL-249-R50;** **Resistive electrode 70mm BTL-249-R70;** **Basic UDI-DI:** **++B108249APEUX7**	Class IIb non-implantable	BTL-6000 TR-Therapy BTL-6000 TR-Therapy Pro BTL-6000 TR-Therapy Elite	10410-2017-CE-CZS-NA-PS Rev. 2.0; 2460
BTL-CPMotion K EASY; **BTL-CPMotion K PRO;** **BTL-CPMotion K ELITE** **Basic UDI-DI:** **++B108053PDEUZ8**	Class IIa	BTL-CPMotion BTL-CPMotion K EASY BTL-CPMotion K PRO BTL-CPMotion K ELITE	10409-2017-CE-CZS-NA-PS Rev. 2.0; 2460
Ankle module BTL-093-3 **Basic UDI-DI:** **++B108293ANKLEEU26**	Class IIa	BTL-CPMotion BTL-CPMotion K EASY BTL-CPMotion K PRO	10409-2017-CE-CZS-NA-PS Rev. 2.0; 2460

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB identification
		BTL-CPMotion K ELITE	
BTL-6000 FSWT **Basic UDI-DI:** **++B108094PDEUZK**	Class IIb non-implantable	BTL-6000 FSWT	1000041836I-PA-NA-CZE rev.0.0.; 2460
FSWT applicator BTL-294-1 **Basic UDI-DI:** **++B108294APEUXH**	Class IIb non-implantable	BTL-6000 FSWT	1000041836I-PA-NA-CZE rev.0.0.; 2460
BTL-6000 Super Inductive System Pro; **BTL-6000 Super Inductive System Elite** **Basic UDI-DI:** **++B108099PDELEUSQ**	Class IIa	BTL-6000 Super Inductive System BTL-6000 Super Inductive System Pro BTL-6000 Super Inductive System Elite BTL-6000 Super Inductive System Locus	10406-2017-CE-CZS-NA-PS rev. 2.0; 2460
Planar field applicator BTL-299-1; **Focused field applicator BTL-299-2** **Basic UDI-DI:** **++B108299APEUZ8**	Class IIa	BTL-6000 Super Inductive System BTL-6000 Super Inductive System Pro BTL-6000 Super Inductive System Elite BTL-6000 Super Inductive System Locus	10406-2017-CE-CZS-NA-PS rev. 2.0; 2460
BTL EMSELLA **Basic UDI-DI:** **++B108099PDEMEUSV**	Class IIa	BTL EMSELLA	12056-2018-CE-CZS-NA-PS Rev. 2.0; 2460
BTL Chair Applicator BTL-299-3; **EMSELLA Chair Applicator BTL-299-3;** **EMSELLA Chair Applicator BTL-099-AP-M-3** **Basic UDI-DI:** **++B108299AP13EURE**	Class IIa	EMSELLA Chair Applicator	12056-2018-CE-CZS-NA-PS Rev. 2.0; 2460 For EMSELLA Chair Applicator: 2005/MDD; 0051
BTL-6000 High Intensity Laser 10 W **BTL-6000 High Intensity Laser 20 W** **BTL-6000 High Intensity Laser 30 W**	Class IIb non-implantable	BTL-6000 High Intensity Laser BTL-6000 High Intensity Laser 10 W	1000040546I-PA-NA-CZE rev.0.0; 2460

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB identification
Basic UDI-DI: ++B108043PDEUX7		BTL-6000 High Intensity Laser 20 W BTL-6000 High Intensity Laser 30 W	
Scanning System Easy **Scanning System Elite** **Basic UDI-DI: ++B108451SCAEUVH**	Class IIb non-implantable	BTL-6000 High Intensity Laser BTL-6000 High Intensity Laser 10 W BTL-6000 High Intensity Laser 20 W BTL-6000 High Intensity Laser 30 W	10000405461-PA-NA-CZE rev.0.0; 2460

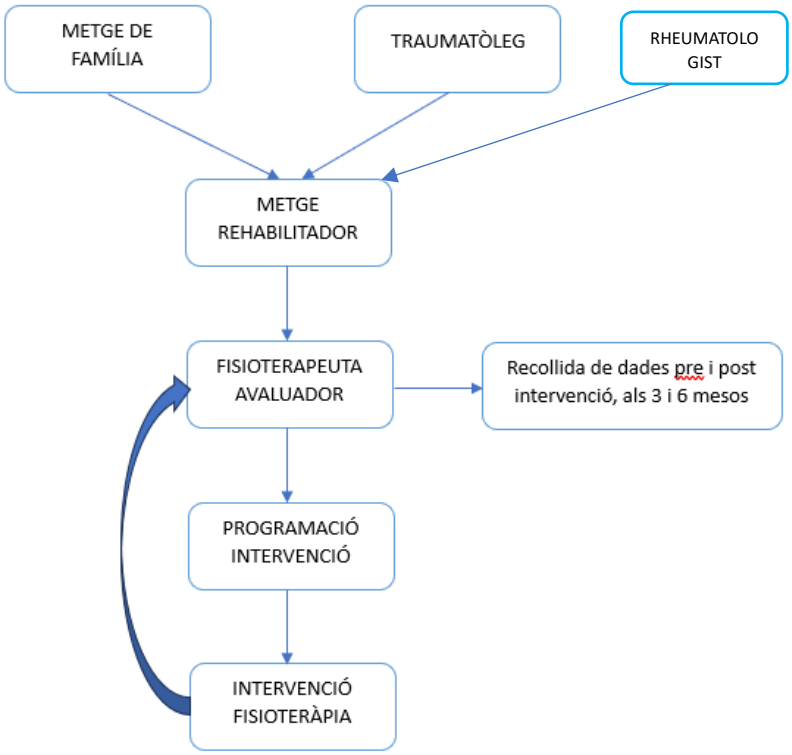
Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB identification
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/06/04	1	Initial issue

ANNEX 12: DIVERSION AND INTERVENTION CIRCUIT



ANNEX 13: PROJECT SCHEDULE

SCHEDULE

Phases	Activity	2025												2026												2027											
		G	F	M	A	Mg	J	E-Mail	S	Or	N	D		G	F	M	A	Mg	J	Jl	S	O	N	D		G	F	M	A	mg	J	Jl	S	O	N	D	
PREPARATION	Project design																																				
	Literature review																																				
	Feasibility analysis																																				
	Prepare draft and report																																				
	Obtain permits and CEIC																																				
	Search for funding																																				
	Training of professionals																																				
	Sample Selection (Convenience Sampling)																																				
	Contacting participants																																				
EXECUTION	Interview with participants (CI, FIP, GI-GC assignment)																																				
	Initial questionnaire - Intervention																																				
	Follow-up at 3 and 6 months																																				
	Data collection and statistical analysis																																				
	Obtaining results																																				
FI	Prepare results report																																				
	Dissemination of project results																																				

G: January, F: February, M: March, A: April, Mg: May, J: June, Jl: July, S: September, O: October, N: November, D: December

ANNEX 14: PARTICIPATING CENTRES AND IPS OF THE CENTRES

PARTICIPATING CENTRES AND IPS OF THE CENTRES

IP Name	Research center/University	Professional category	Role in the project
M. Carmen Sánchez Mato	CAP-II Mataró-Maresme Rehabilitation Service. North Metropolitan Territorial Management. Catalan Institute of Health.	Physiotherapist	Principal Investigator
Luisa Acosta Moreno	Sant Andreu Rehabilitation and Physiotherapy Unit. Territorial Management of Barcelona. Catalan Institute of Health.	Physiotherapist	Research collaborator
Mario Martín Sánchez	Drassanes Rehabilitation and Physiotherapy Unit. Coastal Territorial Management / Left of Barcelona. Catalan Institute of Health.	Physiotherapist	Research collaborator
Anna Escribà Salvans	University of Vic – Central University of Catalonia (UVIC-UCC).	Physiotherapist Doctor	Doctoral Thesis Director
Ramón Arroyo Aljaro	Sant Andreu Rehabilitation and Physiotherapy Unit, Drassanes, Numancia. Territorial Management of Barcelona. Catalan Institute of Health.	Rehabilitation Doctor. PhD	Doctoral Thesis Director

Primary IP Contact:

- **Mail:** csanchezm.ics@gengat.cat
- **Telephone:** 667 61 73 54