**Research Protocol**

# "Effectiveness of osteopathic treatment in patients with nonspecific neck pain. Randomized controlled pragmatic clinical trial "

Identifier: PR407 / 18

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**Research protocol**

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## 1. Administrative Information

### a. Title

Effectiveness of osteopathic treatment in patients with nonspecific neck pain. Randomized controlled pragmatic clinical trial.

### b. Trial registration

Anticipated its registration in ClinicalTrials.gov after its acceptance by the Ethical Committee.

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### c. Protocol version

v. 04: 20/11/2018

### d. Functions and responsibilities

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## 2. Introduction

### a. Justification

In Spain cervical pain affects practically 20% of the population annually[1], while globally it is estimated that between 22% and 77% of the population will suffer cervical pain at some point in their life[2]. Prevalence increases with age, and is more common in women than in men (1.6: 1) [3].

Although the natural evolution of cervical pain tends to improve, the rates of recurrence and chronicity are high[2]. And therefore it becomes an anatomical region of interest in relation to the assessment of the effectiveness and / or effectiveness of the osteopathic therapeutic approach.

Different studies prove the efficacy of various manual therapy techniques applied on the cervical and / or upper dorsal region, suggesting significant positive changes in cervical pain and mobility levels in patients with nonspecific cervical pain.

In this sense, Casanova-Méndez et al[4] showed that the adjustment of high speed and low amplitude, also called "thrust", of the 4th thoracic vertebra (T4) improves mobility and mechanic-sensitivity of the cervical region as well as decreases pain in the same area. All of the improves appears in the short term.

On the other hand, Salom et al[5] concluded that dorsal manipulation using the same thrust technique is more effective than manipulation without thrust to reduce chronic mechanical neck pain of bilateral type.

In relation to the study of interventions that include multiple treatment techniques, we can observe in a study by Saavedra et al[6] that the combination of manipulative techniques at the dorsal and cervical level is more effective than the application of a single cervical technique in the improvement of cervical function. In addition, both approaches show a reduction in cervical pain and increase the range of vertebral movement.

In the same line we find the article by Massarachio et al[7], revealing positive changes in the short term in patients with cervical pain who underwent cervical and dorsal manipulation both in the index of cervical functionality, numerical scale of pain and overall rate of change.

In a recent systematic review and meta-analysis of 2015 carried out by Franke et al[8]. it is suggested that BMT causes clinically relevant effects in pain reduction as well as in functionality in patients with non-specific chronic neck pain.

Taking these studies as a starting point, it is necessary to bear in mind that the reality of the osteopathic approach to the patient is not limited to the use of a single technique, but that the treatment is formed from a set of them. The ultimate goal is to restore mobility and functionality to a specific region, especially taking into account the concepts of individuality and holism.

For this, it is essential to base the treatment on a previous exploration, and there is evidence of a lack of clinical trials with a perspective based on the result of that previous exploration, taking into account again the individuality of the patient and also the clinical criterion of the therapist. This procedure is more realistic with the usual practice.

On the other hand, it is also necessary to evaluate, as different studies conclude[9,10], how the application of osteopathic treatment can be conditioned in the final result at different doses.

In this sense, the latest revision of 2017 of the Clinical Practice Guideline for cervical pain[2] indicates that the dose in terms of intensity, frequency and duration are variable and do not allow to transfer it to practice reliably. It adds as a method to find an adequate dose of treatment the combination of an original test of dose descriptions with clinical judgment, taking into account the principles of physical exercise, movement, pain science and patient preferences.

Lastly, two Cochrane reviews show that both manual therapy[11] and exercise therapy[12] are effective in the treatment of patients with cervical pain. Although later a meta-analysis[13] of Fredin et al. (2017) concluded that the combination of manual therapy and exercises does not seem to be more effective than the practice of physical exercise in isolation.

## b. Goals

Main goal:

The effectiveness of osteopathic treatment will be evaluated in comparison with an exercise plan in patients with nonspecific cervical pain.

Secondary objective:

The result of the treatment applied in different temporal frequencies will be compared.

## c. Trial Design

Randomized, pragmatic, double-blind controlled clinical trial.

## 3. Methods

### a. Scope of the study

The participants will be recruited in the following osteopathy services, where the therapeutic intervention will be carried out:

- Centre Integrosalus (c/ d'Anselm Clavé, 8 – 08348 – Cabrils. Barcelona)
- Centre Axis (c/ de Castelló, 5 - 08770 - Sant Sadurní d'Anoia. Barcelona)
- Clínica d'Osteopatia Horta (c/ Duero, 68 - 08031 – Horta. Barcelona)

### b. Selection criteria

Inclusion criteria:

The sample will be formed by patients between the ages of 18 and 75 years, who present cervical pain of any intensity and duration, and with a minimum score of 10 points on the Neck Disability Index (NDI)[14,15].

Exclusion criteria:

Patients who present at the time of recruitment other pathologies or elements that may condition cervical pain, such as: acute shoulder tendinopathy, cervical radiculopathy, chronic diseases of general musculoskeletal involvement (Chronic Fatigue Syndrome and / or Fibromyalgia). Similarly, patients suffering from any type of vertiginous syndrome, who have suffered a whiplash in the last year or who are or have been under treatment for cervical pain in the last 3 months will also be excluded.

The taking of anti-inflammatories by the patient is not taken as a measure of exclusion. If the patient is under pharmacological treatment, it will be recorded and will be taken into account as a co-intervention. However, this treatment will not be modified under any circumstances nor will it be grounds for exclusion from the study.

### c. Interventions

The test will be carried out with 3 branches (2 experimental + 1 control).

- All groups (1, 2 and 3) will conduct a home-based pattern of combined exercises based on stretching, active anti-resisted exercises and joint mobility exercises focused on the cervico-dorsal and scapulo-thoracic regions. Whose clinical effectiveness has shown significant positive changes in pain levels and cervical functionality[12,13,16].

- The two experimental groups (group 1 and group 2) will also receive Osteopathic Manipulative Treatment (OMT) whose description is detailed below: (description based on the TIDier[17] intervention report guide).

The TMO is a 100% manual intervention that is applied individually with a direct contact between therapist and patient.

- Groups 1 and 2 will receive 3 sessions of BMT.
    - Group 1 will receive 3 sessions with a weekly frequency (with + -2 days of margin: between 5 and 9 days).
    - Group 2 will receive 3 sessions at the rate of one session every 3 weeks (with + -2 days of margin: between 19-23 days).

The clinical experience of the therapists participating in the intervention indicates that 3 sessions could be a sufficient number to achieve changes in the clinic of patients with nonspecific cervical pain and that these may be clinically significant, either immediately after the intervention and in the middle. term (1 month post-intervention).

From the same clinical experience it is considered that an interval of between 1 and 3 weeks is the most common during the course of a treatment to a patient with nonspecific neck pain.

Therefore, it is considered necessary to compare whether there may be differences applying a greater or lesser frequency within the most usual range of applied treatment.

**d. Procedures**

At the beginning of the 1st session, a battery of questions will be made as an anamnesis with the objective of evidencing possible risk factors at the therapeutic level (see **Appendix 4**. Patient data collection form). The presence of one or more risk factors will suppose the exclusion of the patient from the study.

Next, a brief osteopathic musculoskeletal evaluation will be made to the patient. This exploration will follow a standardized protocol for all patients in the experimental groups (1 and 2).

The tests to be carried out will be:

- Observation (standing patient):
    - Assessment of the anterior projection of the head
    - Assessment of the variation in the physiological curves of the spine
- Active test of the cervical spine with the patient in a sitting position.
    - Flexo-Extension / Rotations / Lateral inclinations
- Segmental test of joint mobility of the cervical and dorsal spine (patient in sitting and supine position)
- Passive mobility test of the cervical spine (patient in the supine position):
    - Flexo-Extension / Rotations / Lateral inclinations

The combination of exercises scheduled at home for all groups is based on the conclusions of different studies[12,13,16], and will consist of:

- Self-resisted active exercise in flexion, rotations and inclinations of the cervical spine.
- Active mobility in its maximum travel (without forcing pain) in flexion, rotations and inclinations of the cervical spine.
- Stretching upper trapezius muscles and scalenes.
- Active mobility in circumferential joints of the glenohoumeral joint, and in flexo-extension of the thoracic spine.

Said guideline will be shown to the patient during the first visit, and will be accompanied by a visual support with the detail so that he remembers it and can do it at his home.

The work schedule will be carried out for 7 weeks, at a rate of 5 sessions per week.

It will be the patient himself who will keep a diary record of the activity carried out during the weeks that the trial lasts. The diary will be facilitated by the therapists, and in it the exercises to be performed will be indicated.

For groups 1 and 2, a total of 3 techniques selected from a list of 7 available techniques common to all centers will be applied in each session. The choice of techniques will be based on the results of the examination performed, the particularities of the patient and the clinical experience of the osteopath. In each

session the techniques can change under the criteria of the osteopath. However, they will always be 3 and always within the list of available techniques.

The TMO techniques that may be applied will be the following:

*See the full description of the type of techniques in Glossary Of Osteopathic Terminology, 2011[18]

1. Technique of Inhibition of the suboccipital muscles[19]

Objectives: achieve a relaxation in the short muscle that joins the occipital bone with the C1 and C2 vertebrae and associated vascular and neurological structures, as well as alleviating the associated muscular tension through the insertion of the superior fibers of the trapezius muscle in the same region occipital.

2. Functional technique for the middle and deep cervical fascia[20]

Objectives: to relax the fascial and muscular tissues that make up the anterior muscular bundle of the neck that allows a better alignment of the cervical spine in the antero-posterior projection of the head with respect to the thorax.

3. High-speed cervical spine technique (Cervical wheel C1-C6) [21]
4. High-speed technique in the cervico-dorsal junction (prone position) [21]
5. High speed technique in dorsal column (D1-D12) - (Dog Technique) [21]

Objectives for techniques 3, 4 and 5: recover mobility in specific vertebral segments that present somatic dysfunction, as well as influence primary afferent

neurons in the para-spinal tissue, the motor control system and the pain processing[22].

The term Somatic dysfunction is part of the osteopathic terminology and is defined as "Alterations in the function of the components related to the somatic system: skeletal, articular and myofascial structures and their related vascular, neural and lymphatic elements" [18]

6. Muscle stretching technique of the diaphragm (supine decubitus) [23]

Objectives: to reduce muscle tension by allowing better mobility of the thoracic cage and a better balance of the pressures on the thoracic / abdominal cavity. In the same way, better mobility on the cervical spine.

7. Thorax joint mobility technique (long lever) [21]

Objectives: to improve the mechanics of thoracic mobility, both at the level of the anterior thoracic cage and lateral and posterior, allowing an improvement in the cervical-thoracic mechanical function.

## e. Variables

Main Variable:

- o Neck Disability Index (NDI).

This index is the most used in cervical pain assessments[14]. It is a test of 10 questions with 6 possible answers, which punctuate aspects such as the intensity of cervical pain or the degree of limitation in the main activities of daily life.

The score covers the range of 0 to 50 points, the degree of involvement in cervical functionality being greater the higher the score obtained in the test. We establish the minimum change to be detected (minimum clinically relevant change) at 5 points. The Spanish version of the NDI will be used, validated by Andrade Ortega,JA et al.[24]

Secondary Variable:

- o Degree of general quality of life, through the SF-36 health questionnaire[25].

The data will be reported in the form of a report by the patient himself, who will receive via e-mail (whenever possible) or in printed form the questionnaire to be completed and will deliver to the same centre in which the intervention has been carried out.

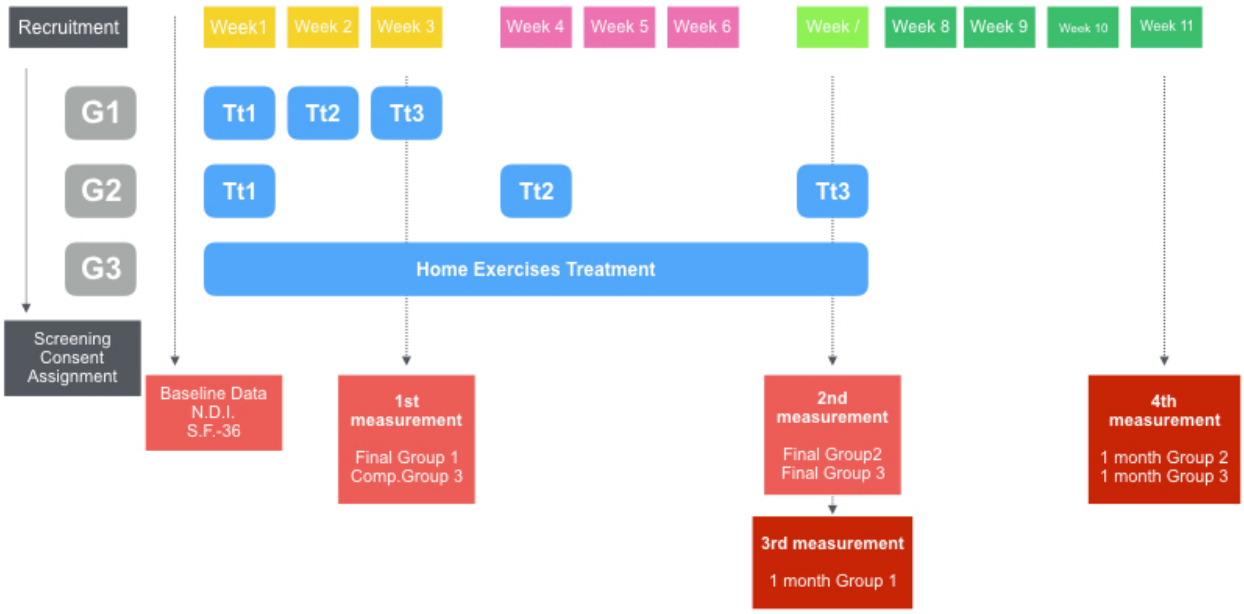
Adverse effects: A record of any adverse effects that may be occur during the study, these being detailed in the same patient control sheet (**see Appendix 4**).

**Tracing:**

NDI: The measurements at the beginning of the study (baseline measures), 3 days after the last intervention and after 1 month post-study.

Quality of life (SF-36): The measurements in this case will be taken at the beginning of the study (baseline measures) and after 1 month post-study.

## f. Participants Schedule



## g. Sample

The sample size has been calculated following the following parameters:

Randomized clinical trial, with 3 branches of study, a minimum detectable change in the NDI of 5 points (10%), 80% statistical power and a standard deviation of 7.

Accepting an alpha risk of 0.05 and a beta risk of less than 0.2 in a bilateral contrast will require 46 subjects in each group, that is, an n = 132.

The value of estimated losses is 10% of the total.

## h. Randomization

A pragmatic experimental comparative trial with three branches of study (osteopathic treatment with 2 different dosages versus active muscle exercise) is proposed.

After obtaining informed consent (see **Appendix 1**. Information sheet and Informed Consent), patients who meet the inclusion criteria will be awarded to the study groups following a random sequence generated by computer and stratified by each centre. The assignment through the opaque envelope system will guarantee the concealment of said assignment.

The generation of the sequence and the preparation of the opaque envelopes will be done by an external researcher not involved in the interventions.

The recruitment of the participants, and their assignment to the study groups will be carried out by the same people in charge of carrying out the intervention..

### i. Masking

A double masking is proposed.

Three active interventions are compared.

The patients will be blinded in relation to the study group they belong to, ensuring the masking of the participants.

The data that is intended to be obtained for its analysis are of a self-reported nature and will be collected and administered by an external investigator not linked to the interventions, ensuring the masking of the evaluator.

Due to the nature of the interventions, masking of therapists is not possible.

## 4. Ethics

This protocol will be presented at the Escola d'Osteopatia de Barcelona, as part of the development of a research project to obtain the D.O. (diploma in osteopathy). Prior to the development of the trial, it will be presented to the Clinical Ethics Committee of Bellvitge Hospital for approval.

The recruitment of participants will be done under the signature of the informed consent (see **Appendix 1**).

The centres where the study will be carried out are of a private nature, and the development of the trial will not entail any cost for the patient in the interventions received.

The people in charge of informing the study, obtaining the signature of the informed consents and carrying out the interventions will be the OH, ES and DP researchers.

The patient may leave the study at any time, without prior notice and without specifying the reason.

Participation in this clinical trial by patients does not imply any increase in risk in relation to usual clinical practice. Comparative interventions are common in osteopathic manual practice.

Randomization, preparation of opaque envelopes and data monitoring will be carried out by GA.

The clinical and personal data of the participants will be coded numerically, and

this relationship is kept in the custody of the research team. Likewise, the processing of these data will be in accordance with the provisions of the LOPD 15/1999 and the General Data Protection Regulation (EU) 2016/679. In no case will this information be disclosed to people outside the study.

This clinical study will be carried out in accordance with the principles of the Declaration of Helsinki (Fortaleza, 2013).

Declaration of conflicts of interest: No.

## 5. Appendices

### a. Appendix 1 (Information Sheet and Informed Consent)

***"Effectiveness of the osteopathic treatment in patients with nonspecific cervical pain. Randomized controlled pragmatic clinical trial "***

***Principal Investigators:***

** Óscar Hernandez (IntegroSalus), Edgar Segarra (Osteopatia Horta Clinic), David Puertas (Center Axis)*

## ***Informational page***

Dear Mr / Mrs:

The study, in which we propose to participate, constitutes a scientific investigation in the field of cervical pain. This research is framed in the context of a final Master project. It is a study whose intervention does not generate any type of cost for the patient nor an increased risk in relation to the usual clinical practice, given that the interventions compared are common in osteopathic manual practice. The objective of this study is to compare the effect of 3 interventions. All of them have been shown to have positive effects in reducing cervical pain. Two of the interventions constitute different modalities of manual therapy, and the third is based on a specific exercise plan for cervical pain. If you agree to participate in this study, you will be required to complete two questionnaires related to cervical pain (50 questions) and quality of life (36 questions). The estimated time to complete the forms is 8 minutes and must be completed in three moments of the study (start, end of treatment, 1 month post-treatment). You will receive them by email again or you can fill them out electronically at any of the centers attached to the study

Participation is **VOLUNTARY**. At any time you can leave the study without giving any explanation. All personal data obtained in this study will be treated confidentially in accordance with the Organic Law of Protection of Personal Data 15/99 and the Regulation (EU) 2016/679 General Data Protection. The information obtained will be used exclusively for the specific purposes of this study, and will be coded to maintain the anonymity of the participants at all times.

Participants have the right to access, rectification, cancellation, opposition, to limit the processing of their data that are incorrect, to request a copy of them, or to transfer the data collected (portability) to a third party, and to exercise These rights must be communicated to the principal investigator.

In case of transfer of data to third countries outside the EU or the European Economic Area (EEA), the researcher will establish the necessary measures to guarantee a level of data protection equivalent to that granted by European legislation.

The research team will keep the records of this clinical study for a period of not less than 25 years.

* This study project has been previously authorized by an independent Research Ethics Committee, which ensures respect for the rights, safety and well-being of people who participate in research projects.

***"Effectiveness of the osteopathic treatment in patients with nonspecific cervical pain. Randomized controlled pragmatic clinical trial "***

***Principal Investigators:***

** Óscar Hernandez (IntegroSalus), Edgar Segarra (Osteopatia Horta Clinic), David Puertas (Center Axis)*

## ***Informed Consent***

**We request your consent to participate in this study**, which means that we can use the information obtained in the survey and record and analyse it later in the framework of this scientific research. Of course, if you do not participate in the study, **in no case will this influence the professional care provided**.

**PATIENT WRITTEN CONSENT**

I,....., I read the sheet

information that they have given me, I have been able to ask questions about the study, I have received enough information about it and I have been able to consult my doubts

with Mr .....

I understand that acceptance is voluntary and that I can leave the study whenever I want without giving explanations, so I agree to participate in the study.

Signature of the patient

Signature of the osteopath attending to him

## b. **Appendix 2** (NDI – Neck Disability Index Questionnaire)

***SPANISH VERSION REFORMULATED OF "NECK DISABILITY INDEX"*** [27]

Name: _____ Age: _____
Date: _____
Address: _____
Profession: _____

Please read the instructions carefully:
This questionnaire has been designed to give your doctor information about how neck pain affects your daily life. Please fill in all possible questions and mark on each one ONLY THE ANSWER THAT APPROXES TO YOUR CASE. Although more than one answer may apply to your question, check only the one that best represents your problem.

***Question I: Neck pain intensity***

☐ I have no pain right now
☐ The pain is very mild at this time
☐ The pain is moderate right now
☐ The pain is strong right now
☐ The pain is very strong right now
☐ At this time the pain is the worst one can imagine

***Question II: Personal care (washing, dressing, etc.)***

☐ I can take care of myself normally without increasing pain
☐ I can take care of myself normally, but this increases my pain
☐ Taking care of me hurts so I have to do it slowly and carefully
☐ Although I need some help, I manage for almost all my care
☐ Every day I need help for most of my care
☐ I can't get dressed, I wash with difficulty and I stay in bed

***Question III: Lifting weights***

☐ I can lift heavy objects without increasing pain
☐ I can lift heavy objects, but the pain increases
☐ Pain prevents me from lifting heavy objects from the ground, but I can do it if they are placed in an easy place, such as on a table
☐ Pain prevents me from lifting heavy objects from the ground, but I can lift medium or light objects if they are placed in an easy place
☐ I can only lift very light objects
☐ I cannot lift or carry any weight

***Question IV: Reading***

☐ I can read everything I want without my neck hurting
☐ I can read everything I want with a slight pain in the neck
☐ I can read everything I want with moderate neck pain
☐ I can't read everything I want due to moderate neck pain
☐ I can barely read because of the great pain in my neck
☐ I can't read anything at all

***Question V: Headache***

☐ I have no headache
☐ Sometimes I have a small headache
☐ Sometimes I have a moderate headache
☐ I often have a moderate headache
☐ I often have a severe headache
☐ I have almost continuous headache

***Question VI: Concentrate on something***

☐ I totally focus on something when I want without difficulty
☐ I totally focus on something when I want with some difficulty
☐ I have some difficulty concentrating when I want
☐ I have enough difficulty concentrating when I want
☐ I have a hard time concentrating when I want
☐ I can never concentrate

***Question VII: Work and usual activities***

☐ I can work all I want
☐ I can do my usual job, but no more
☐ I can do almost all my usual work, but no more
☐ I can't do my usual job
☐ I can hardly do some kind of work
☐ I can't work on anything

***Question VIII: Driving vehicles***

☐ I can drive without neck pain
☐ I can drive everything I want, but with a slight neck pain
☐ I can drive everything I want, but with moderate neck pain
☐ I can't drive everything I want due to neck pain
☐ I can barely drive due to intense neck pain
☐ I can't drive anything because of neck pain

***Question IX: Dream***

☐ I have no problem sleeping
☐ Neck pain makes me lose less than 1 hour of sleep every night
☐ Neck pain makes me lose 1 to 2 hours of sleep every night
☐ Neck pain makes me lose 2 to 3 hours of sleep every night
☐ Neck pain makes me lose 3 to 5 hours of sleep every night
☐ Neck pain makes me lose 5 to 7 hours of sleep every night

***Question X: Leisure Activities***

☐ I can do all my leisure activities without neck pain
☐ I can do all my leisure activities with some neck pain
☐ I can't do some of my leisure activities because of neck pain
☐ I can only do a few leisure activities because of neck pain
☐ I can barely do the things I like because of neck pain
☐ I cannot do any leisure activity

**c. Appendix 3** (SF-36 v.2 Questionnaire)

# Your Health and Well-Being

## HEALTH STATUS SURVEY SF-36

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**Participant ID:** _____ **Protocol** 0102

**Center:** _____ **Visit Number:** _____

**This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities.** ***Thank you for completing this survey!***

**For each of the following questions, please mark an ☒ in the one box that best describes your answer.**

**1. In general, would you say your health is:**

| Excellent | Very good | Good | Fair | Poor |
|---|---|---|---|---|
| ☐1 | ☐2 | ☐3 | ☐4 | ☐5 |

**2. <u>Compared to one year ago</u>, how would you rate your health in general <u>now</u>?**

| Much better now than one year ago | Somewhat better now than one year ago | About the same as one year ago | Somewhat worse now than one year ago | Much worse now than one year ago |
|---|---|---|---|---|
| ☐1 | ☐2 | ☐3 | ☐4 | ☐5 |

**3. The following questions are about activities you might do during a typical day. Does <u>your health now limit you</u> in these activities? If so, how much?**

| | Yes, limited a lot | Yes, limited a little | No, not limited at all |
|---|---|---|---|
| a <u>Vigorous activities</u>, such as running, lifting heavy objects, participating in strenuous sports | ☐ 1 | ☐ 2 | ☐ 3 |
| b <u>Moderate activities</u>, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf | ☐ 1 | ☐ 2 | ☐ 3 |
| c Lifting or carrying groceries | ☐ 1 | ☐ 2 | ☐ 3 |
| d Climbing <u>several</u> flights of stairs | ☐ 1 | ☐ 2 | ☐ 3 |
| e Climbing <u>one</u> flight of stairs | ☐ 1 | ☐ 2 | ☐ 3 |
| f Bending, kneeling, or stooping | ☐ 1 | ☐ 2 | ☐ 3 |
| g Walking <u>more than a mile</u> | ☐ 1 | ☐ 2 | ☐ 3 |
| h Walking <u>several hundred yards</u> | ☐ 1 | ☐ 2 | ☐ 3 |
| i Walking <u>one hundred yards</u> | ☐ 1 | ☐ 2 | ☐ 3 |
| j Bathing or dressing yourself | ☐ 1 | ☐ 2 | ☐ 3 |

**4. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health?**

| | All of the time | Most of the time | Some of the time | A little of the time | None of the time |
|---|---|---|---|---|---|
| a Cut down on the amount of time you spent on work or other activities | ☐1 | ☐2 | ☐3 | ☐4 | ☐5 |
| b Accomplished less than you would like | ☐1 | ☐2 | ☐3 | ☐4 | ☐5 |
| c Were limited in the kind of work or other activities | ☐1 | ☐2 | ☐3 | ☐4 | ☐5 |
| d Had difficulty performing the work or other activities (for example, it took extra effort) | ☐1 | ☐2 | ☐3 | ☐4 | ☐5 |

**5. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?**

| | All of the time | Most of the time | Some of the time | A little of the time | None of the time |
|---|---|---|---|---|---|
| a Cut down on the amount of time you spent on work or other activities | ☐1 | ☐2 | ☐3 | ☐4 | ☐5 |
| b Accomplished less than you would like | ☐1 | ☐2 | ☐3 | ☐4 | ☐5 |
| c Did work or other activities less carefully than usual | ☐1 | ☐2 | ☐3 | ☐4 | ☐5 |

6. **During the <u>past 4 weeks</u>, to what extent has your <u>physical health or emotional problems</u> interfered with your normal social activities with family, friends, neighbors, or groups?**

| Not at all | Slightly | Moderately | Quite a bit | Extremely |
|---|---|---|---|---|
| ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |

7. **How much <u>bodily</u> pain have you had during the <u>past 4 weeks</u>?**

| None | Very mild | Mild | Moderate | Severe | Very Severe |
|---|---|---|---|---|---|
| ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 | ☐ 6 |

8. **During the <u>past 4 weeks</u>, how much did <u>pain</u> interfere with your normal work (including both work outside the home and housework)?**

| Not at all | A little bit | Moderately | Quite a bit | Extremely |
|---|---|---|---|---|
| ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |

9. **These questions are about how you feel and how things have been with you <u>during the past 4 weeks</u>. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the <u>past 4 weeks</u>...**

| | All of the time | Most of the time | Some of the time | A little of the time | None of the time |
|---|---|---|---|---|---|
| a Did you feel full of life? | ☐1 | ☐2 | ☐3 | ☐4 | ☐5 |
| b Have you been very nervous? | ☐1 | ☐2 | ☐3 | ☐4 | ☐5 |
| c Have you felt so down in the dumps that nothing could cheer you up? | ☐1 | ☐2 | ☐3 | ☐4 | ☐5 |
| d Have you felt calm and peaceful? | ☐1 | ☐2 | ☐3 | ☐4 | ☐5 |
| e Did you have a lot of energy? | ☐1 | ☐2 | ☐3 | ☐4 | ☐5 |
| f Have you felt downhearted and depressed? | ☐1 | ☐2 | ☐3 | ☐4 | ☐5 |
| g Did you feel worn out? | ☐1 | ☐2 | ☐3 | ☐4 | ☐5 |
| h Have you been happy? | ☐1 | ☐2 | ☐3 | ☐4 | ☐5 |
| i Did you feel tired? | ☐1 | ☐2 | ☐3 | ☐4 | ☐5 |

10. **During the <u>past 4 weeks</u>, how much of the time has your <u>physical health or emotional problems</u> interfered with your social activities (like visiting friends, relatives, etc.)?**

| All of the time | Most of the time | Some of the time | A little of the time | None of the time |
|---|---|---|---|---|
| ☐1 | ☐2 | ☐3 | ☐4 | ☐5 |

**11. How TRUE or FALSE is <u>each</u> of the following statements for you?**

| | Definitely true | Mostly true | Don't know | Mostly false | Definitely false |
|---|---|---|---|---|---|
| a. I seem to get sick a little easier than other people | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |
| b. I am as healthy as anybody I know | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |
| c. I expect my health to get worse | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |
| d. My health is excellent | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |

***THANK YOU FOR COMPLETING THESE QUESTIONS!***

## d. **Appendix 4** (Patient data collection form)

Patient's Name: _____ Sex: _____

Assigned Group: _____ Identification: _____ Age: _____

**Anamnesis Exclusion**

- ☐ Discopathy diagnosed - Level: _____
- ☐ Previous Radiculopathies: _____
- ☐ Surgical interventions: _____
- ☐ Osteosynthesis material carrier: _____
- ☐ Pacemaker carrier
- ☐ Previous spine fractures - Level: _____
- ☐ HTA (medicated / unmedicated) - Value: _____
- ☐ Osteoporosis diagnosed
- ☐ Rheumatic Diseases: _____
- ☐ Cancer history: _____
- ☐ Current medication (corticosteroids) _____ - -
- ☐ Current medication (anticoagulants) _____ - -
- ☐ In current treatment or in anticipation of oral implants or orthodontics for the duration of the study.

MEDICATION: _____ - - _____ - -

_____ - - _____ - -

| **Expl #1** | **Expl #2** | **Expl #3** |
|---|---|---|
| Obs: _____ | Obs: _____ | Obs: _____ |
| Active T.: _____ | Active T.: _____ | Active T.: _____ |
| Passive T.: _____ | Passive T.: _____ | Passive T.: _____ |
| Segm T: _____ | Segm T: _____ | Segm T: _____ |
| **TTm #1 __ / __ / __** | **TTm #2 __ / __ / __** | **TTm #3 __ / __ / __** |
| ☐ Suboccipital inhibition | ☐ Suboccipital inhibition | ☐ Suboccipital inhibition |
| ☐ Cervical fascia | ☐ Cervical fascia | ☐ Cervical fascia |
| ☐ High cervical speed (C1-C7) | ☐ High cervical speed (C1-C7) | ☐ High cervical speed (C1-C7) |
| ☐ High speed CT | ☐ High speed CT | ☐ High speed CT |
| ☐ High back speed (D1-D12) | ☐ High back speed (D1-D12) | ☐ High back speed (D1-D12) |
| ☐ Stretching diaphragm | ☐ Stretching diaphragm | ☐ Stretching diaphragm |
| ☐ Chest joint mobility | ☐ Chest joint mobility | ☐ Chest joint mobility |
| **Adverse Effects** | **Adverse Effects** | **Adverse Effects** |

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