University of West Attica

Health and Care Sciences

Department of Physiotherapy

Date: 18/05/2023

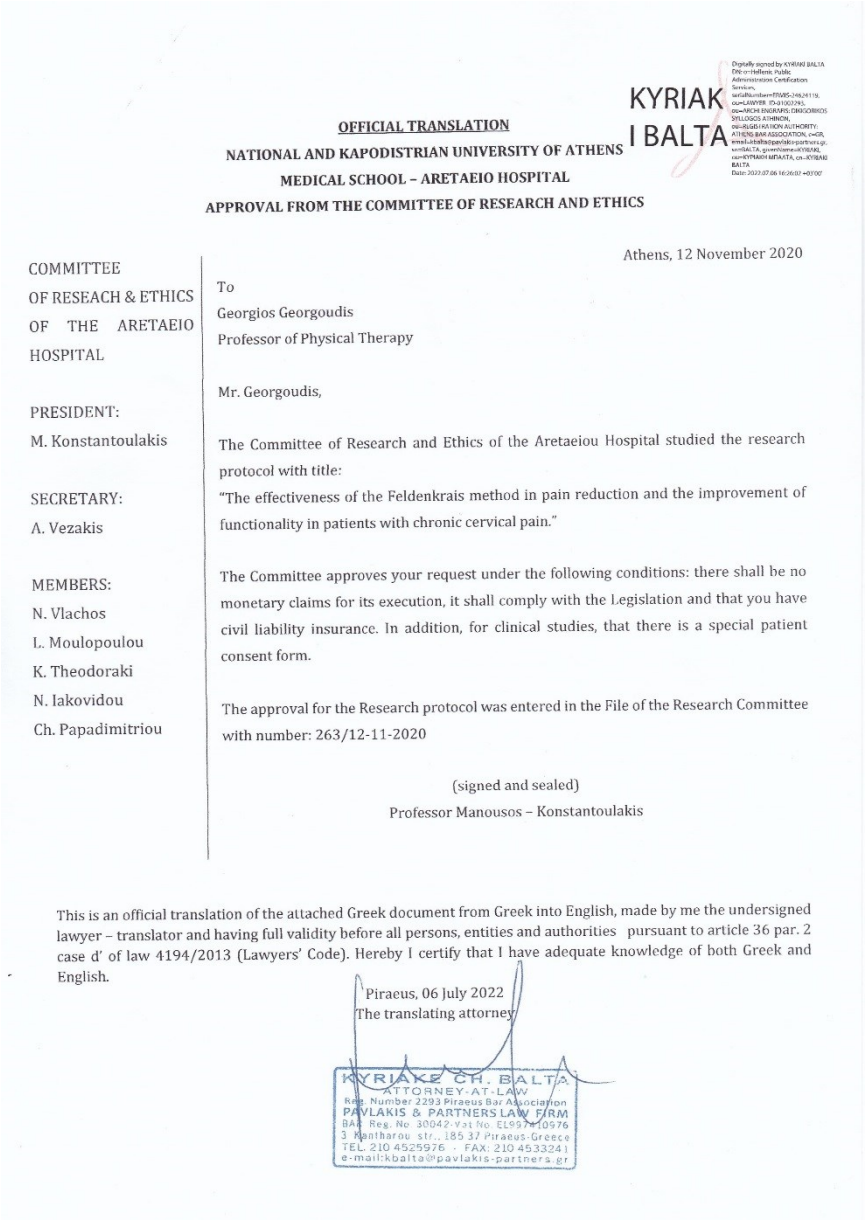
Study Protocol with Statistical Analysis Plan and Informed Consent Form

"The Effectiveness of the Feldenkrais Method in Reducing Pain and Improving Functionality in Patients with Chronic Neck Pain"

CONTENTS

1. INFORMED CONSENT FORM

The final research proposal of the study has been submitted and approved both by the main body that concerns it, which is the University First Anesthesiology Clinic and the Pain Department of the Aretaeio hospital (Approval No. 263/12-11-2020) (Document 1), as well as by the Research Ethics and Ethics Committee of the University of West Attica (UNIWA), with protocol number: 103276/18-12-2020 (Document 2).



OFFICIAL TRANSLATION

NATIONAL AND KAPODISTRIAN UNIVERSITY OF ATHENS

MEDICAL SCHOOL – ARETAEIO HOSPITAL

APPROVAL FROM THE COMMITTEE OF RESEARCH AND ETHICS

KYRIAKI BALTA

Athens, 12 November 2020

COMMITTEE OF RESEACH & ETHICS OF THE ARETAEIO HOSPITAL

PRESIDENT:
M. Konstantoulakis

SECRETARY:
A. Vezakis

MEMBERS:
N. Vlachos
L. Moulopoulou
K. Theodoraki
N. Iakovidou
Ch. Papadimitriou

To
Georgios Georgoudis
Professor of Physical Therapy

Mr. Georgoudis,

The Committee of Research and Ethics of the Aretaeiou Hospital studied the research protocol with title:
"The effectiveness of the Feldenkrais method in pain reduction and the improvement of functionality in patients with chronic cervical pain."

The Committee approves your request under the following conditions: there shall be no monetary claims for its execution, it shall comply with the Legislation and that you have civil liability insurance. In addition, for clinical studies, that there is a special patient consent form.

The approval for the Research protocol was entered in the File of the Research Committee with number: 263/12-11-2020

(signed and sealed)
Professor Manousos – Konstantoulakis

This is an official translation of the attached Greek document from Greek into English, made by me the undersigned lawyer – translator and having full validity before all persons, entities and authorities pursuant to article 36 par. 2 case d' of law 4194/2013 (Lawyers' Code). Hereby I certify that I have adequate knowledge of both Greek and English.

Piraeus, 06 July 2022
The translating attorney

KYRIAKE CH. BALTA
ATTORNEY-AT-LAW
Reg. Number 2293 Piraeus Bar Association
PAVLAKIS & PARTNERS LAW FIRM
BAR Reg. No. 30042 Vat No. EL997410576
3 Kantharou str., 185 37 Piraeus-Greece
TEL. 210 4525976 · FAX: 210 4533241
e-mail:kbalta@pavlakis-partners.gr

Document 1. Decision by the Research & Ethics Committee of Aretaeio Hospital

KYRIA KI BALTA

Digitally signed by KYRIAKI BALTA
DN: cn=Hellenic Public Administration Certification Services, serialNumber=EMΣ-24624119, tin=LAWYER ID-61002293, ou=ARCHI ENGRAPIS DIKIGORIKOS SILLOGOS ATHINON, o=REGISTRATION AUTHORITY: ATHENS BAR ASSOCIATION, c=GR, email=kbalta@pavlakis-partners.gr, sn=BALTA, givenName=KYRIAKI, cn=KYRIAKH MPAATA, cn=KYRIAKI BALTA
Date: 2022.07.06 10:20:37 +03'00'

OFFICIAL TRANSLATION

UniWA – 103604- 22/12/2020

RESEARCH ETHICS COMMITTEE

UNIVERSITY OF WEST ATTICA

EGALEO PARK CAMPUS
Postal address: Agiou Spyridonos, Aigaleo, P.C. 12243
Tel: 2105387294
e-mail: ethics@uniwa.gr
Information: Evagelia Kapoutsi

Egaleo 21/12/2020

SUBJECT: Reply to your application

TO: Georgios Georgoudis
Cc: Charalampos Skordis

PROPOSAL APPROVAL

We inform you that on the 23rd meeting with date 21-12-2020 the Research Ethics Committee (R.E.C.) of the University of West Attica (UniWA) examined through teleconference the content of the research protocol titled "The effectiveness of the Feldenkrais method in pain reduction and the improvement of functionality in patients with chronic cervical pain." With protocol number 103276/18-12-2020 and Scientific Supervisor Mr. Georgoudis Georgios.

Considering:

1. The application form
2. The research protocol
3. The consent forms of those participating in the research

The Committee judged that it is not breach the relevant legislation and conforms to the generally accepted moral code of research ethics and deontology of research integrity, with regards to the research content and mode of conducting research.

The R.E.C. director
(digital signature)
Dr. Anna Deltsidou
Professor

This is an official translation of the attached Greek document from Greek into English, made by me the undersigned lawyer – translator and having full validity before all persons, entities and authorities pursuant to article 36 par. 2 case d' of law 4194/2013 (Lawyers' Code). Hereby I certify that I have adequate knowledge of both Greek and English.

Piraeus, 06 July 2022
The translating attorney

KYRIAKE CH. BALTA
ATTORNEY-AT-LAW
Reg. Number 2293 Piraeus Bar Association
PAVLAKIS & PARTNERS LAW FIRM
BAR Reg. No. 30042-Vat No. EL997410976
3 Kantharou str., 185 37 Piraeus-Greece
TEL. 210 4525976 - FAX. 210 4533241
e-mail:kbalta@pavlakis-partners.gr

Document 2. Decision by the Research Ethics and Ethics Committee of the University of West Attica (UNIWA)

2. FINAL CONFIGURATION OF RESEARCH PROTOCOL

2.1. PURPOSE

The present study was designed to examine whether and to what extent the application of the Awareness Through Movement (ATM) technique of the Feldenkrais method (FM) will reduce pain, improve functionality and will positively affect psychosomatic parameters of pain in patients with chronic neck pain, both as a single intervention (1st arm) and compared to a protocol of biomedical acupuncture combined with stretching (2nd arm).

2.2. RESEARCH DESIGN

The present study is a single blind randomized controlled clinical trial with an active control element, where the intervention is the ATM technique and the standard treatment given to the control group is the combination of acupuncture and stretching.

2.3. RESEARCH HYPOTHESISES

Two main research questions are formulated regarding the effectiveness of ATM versus a standard treatment regimen consisting of acupuncture and stretching, but also the effectiveness of ATM as monotherapy, which will be investigated through appropriate statistical controls. The formal basis of statistical tests is the null hypothesis under which there is no association between the exposure and the outcome (Killeen, 2005). Starting from the assumption of no relationship, statistical tests quantify the probability that the observed relationship was observed by chance, due to the random sampling distribution. When the null hypothesis cannot be rejected then the observed relationship is attributable to chance rather than a true effect of the exposure on the outcome (Banerjee *et al.*, 2009).

Thus, the null hypotheses to be tested are formulated as follows:

- Research question 1: Effectiveness of ATM (intervention group before the intervention vs. the same group after the intervention)

- Null hypothesis H_{0A1}: The application of ATM does not affect the sensitivity assessed by the Pain Pressure Threshold (PPT) measured with an algometer in patients with chronic neck pain (main hypothesis).
- Null hypothesis H_{0A2}: The application of ATM does not affect the range of motion (ROM) and kinesthesia recorded with a 3D inertial motion MOOVER sensor in patients with chronic neck pain (secondary hypothesis).
- Null hypothesis $H_{0A3:}$ The application of ATM does not affect the strength of deep neck flexor muscles as measured by Chattanooga Stabilizer Biofeedback Pressure in patients with chronic pain in the cervical spine (secondary hypothesis).
- Null hypothesis $H_{0A4:}$ The application of ATM does not affect respiratory function assessed by spirometer in patients with chronic neck pain (secondary hypothesis).
- Null hypothesis H_{0A5}: The application of ATM does not affect the pain in the cervical spine in terms of its intensity and quality, i.e., its sensory, emotional and behavioral dimensions using the McGill Pain Questionnaire-short form (SFMPQ) as well as the degree of pain catastrophizing measured by the Pain Catastrophizing Scale (PCS) in patients with chronic neck pain (secondary hypothesis).
- Null hypothesis H_{0A6}: The application of ATM does not affect the functionality recorded with the Neck Disability Index (NDI) in patients with chronic pain in the cervical spine (secondary hypothesis).
- Null hypothesis H_{0A7}: The application of ATM does not affect the psychometric characteristics captured by the Hospital Anxiety & Depression Scale (HADs), the 12-items Health Survey Questionnaire (SF-12) and the Fear Avoidance Beliefs Questionnaire/FABQ_GR in patients with chronic neck pain (secondary hypothesis).
- Null hypothesis $H_{0A8:}$ The application of ATM does not affect kinesiophobia as measured by the Tampa Scale Kinesiophobia/TSK_GR (secondary hypothesis).

- Research question 2: Effectiveness of ATM versus acupuncture-stretching

    - Null hypothesis H_{0B1}: The effect of applying ATM does not differ in reducing sensitivity (PPT) in patients with chronic neck pain from applying acupuncture together with stretching (main hypothesis).
    - Null hypothesis H_{0B2}: The effect of the application of ATM does not differ in the reduction of pain in terms of its intensity and quality, as well as the degree of destructive views about it in patients with chronic neck pain from the application of acupuncture-stretching (secondary hypothesis).
    - Null hypothesis $H_{0B3:}$ The effect of applying ATM does not differ in improving the strength of deep neck flexor muscles in patients with chronic neck pain than applying acupuncture together with stretching (secondary hypothesis).
    - Null hypothesis $H_{0B4:}$ The effect of the application of ATM does not differ in the improvement of respiratory function in patients with chronic neck pain from the application of acupuncture-stretching (secondary hypothesis).
    - Null hypothesis H_{0B5}: The effect of the application of ATM does not differ in the improvement of ROM and kinesthesia in patients with chronic pain in the cervical spine from the application of acupuncture combined with stretching (secondary hypothesis).
    - Null hypothesis H_{0B6}: The effect of the application of ATM does not differ in the improvement of functionality in patients with chronic neck pain from the application of acupuncture-stretching (secondary hypothesis).
    - Null hypothesis H_{0B7}: The effect of the application of ATM does not differ in the improvement of psychometric characteristics in patients with chronic pain in the cervical spine from the application of acupuncture along with stretching (secondary hypothesis).
    - Null hypothesis $H_{0B8:}$ The effect of the application of ATM does not differ from the application of acupuncture-stretching in reducing

kinesiophobia in patients with chronic neck pain (secondary hypothesis).

If the null hypothesis is rejected, i.e., in the case where a chance relationship between the exposure and the outcome is ruled out, the alternative hypothesis is valid, which is equivalent to the existence of a true relationship between the exposure and the outcome of interest. The strength of the alternative hypothesis cannot be tested directly, but only through the initial testing of the null hypothesis (Banerjee *et al.*, 2009).

Thus, the alternative hypotheses to be tested are formulated as follows:

- Research question 1: Effectiveness of ATM

  - Alternative hypothesis H_{1A1}: The application of ATM affects the sensitivity assessed by Pain Pressure Threshold (PPT) measured with an algometer in patients with chronic neck pain (main hypothesis).
  - Alternative hypothesis H_{1A2}: The application of ATM affects range of motion (ROM) and kinesthesia recorded with a 3D inertial motion MOOVER sensor in patients with chronic neck pain (secondary hypothesis).
  - Alternative hypothesis $H_{1A3:}$ The application of ATM affects deep neck flexor muscles strength as measured by Chattanooga Stabilizer Biofeedback Pressure in patients with chronic pain in the cervical spine (secondary hypothesis).
  - Alternative hypothesis $H_{1A4:}$ The application of ATM affects respiratory function assessed by spirometer in patients with chronic neck pain (secondary hypothesis).
  - Alternative hypothesis H_{1A5}: The application of ATM affects the levels of pain in the cervical spine in terms of its intensity and quality, i.e. its sensory, emotional and behavioral dimensions using the McGill Pain Questionnaire-short form (SFMPQ) as well as the degree of pain catastrophizing measured by the Pain

Catastrophizing Scale (PCS) in patients with chronic neck pain (secondary hypothesis).

- Alternative hypothesis H_{1A6}: The application of ATM affects the improvement of the functionality recorded with the Neck Disability Index (NDI) in patients with chronic pain in the cervical spine (secondary hypothesis).
- Alternative hypothesis H_{1A7}: The application of ATM affects the psychometric characteristics captured by the Hospital Anxiety & Depression Scale (HADs), the 12-item Health Survey Questionnaire (SF-12) and the Fear Avoidance Beliefs Questionnaire/FABQ_GR in patients with chronic neck pain (secondary hypothesis).
- Alternative hypothesis $H_{1A8:}$ The application of ATM affects kinesiophobia as measured by the Tampa Scale Kinesiophobia/TSK_GR (secondary hypothesis).

- Research question 2: Effectiveness of ATM versus acupuncture-stretching

- Alternative hypothesis H_{1B1}: The effect of applying ATM differs in reducing sensitivity (PPT) in patients with chronic neck pain from applying acupuncture together with stretching (main hypothesis).
- Alternative hypothesis H_{1B2}: The effect of the application of ATM differs in the reduction of pain in terms of its intensity and quality, as well as the degree of destructive views about it in patients with chronic neck pain from the application of acupuncture-stretching (secondary hypothesis).
- Alternative hypothesis $H_{1B3:}$ The effect of applying ATM differs in improving the strength of deep neck flexor muscles in patients with chronic neck pain from applying acupuncture together with stretching (secondary hypothesis).
- Alternative hypothesis $H_{1B4:}$ The effect of applying ATM differs in improving respiratory function in patients with chronic neck pain from applying acupuncture-stretching (secondary hypothesis).

- Alternative hypothesis H_{1B5}: The effect of the application of ATM differs in the improvement of ROM and kinesthesia in patients with chronic pain in the cervical spine from the application of acupuncture combined with stretching (secondary hypothesis).
- Alternative hypothesis H_{1B6}: The effect of the application of ATM differs in the improvement of functionality in patients with chronic neck pain from the application of acupuncture-stretching (secondary hypothesis).
- Alternative hypothesis H_{1B7}: The effect of the application of ATM differs in the improvement of psychometric characteristics in patients with chronic pain in the cervical spine from the application of acupuncture together with stretching (secondary hypothesis).
- Alternative hypothesis $H_{1B8:}$ The effect of applying ATM differs in reducing kinesiophobia in patients with chronic neck pain from applying acupuncture-stretching (secondary hypothesis).

2.4. OBJECTIVE GOALS

Objectives of the study are summarized in the investigation of differences in the outcomes of interest, i.e. in the measurements for pain sensitivity and intensity (algometer and SFMPQ), functionality (NDI), range of motion (ROM) and kinesthesia (3D inertial motion MOOVER sensor), endurance of deep neck flexor muscles (Chattanooga Stabilizer Biofeedback Pressure), respiratory function (spirometer) and psychometric characteristics (HADs, SF-12, FABQ_GR, PCS). Differences in the outcomes of interest may arise:

a) between the compared groups of the clinical trial [group A- ATM (Intervention Group-IG) versus group B- acupuncture+stretching (A-S) (Control Group)], both at the beginning of the study, as well as after the intervention.

b) between the start time (baseline) and the end time of the study within the A-ATM group (A-ATM group at baseline (Intervention Group Pre-IGpre) versus A-ATM group after the intervention (Intervention Group Post/Intervention Group Post-IGpost) It is worth noting that the comparisons that will be made between the

two time points in group A will be unaffected by the possible residual confounding effect of demographic and other non-time-dependent factors, as is done in the "Self- Controlled Case Series' where each patient acts as his own witness (Louis *et al.*, 1984).

2.5. MATERIAL AND METHOD

2.5.1. SAMPLE

2.5.1.1. SAMPLE CHARACTERISTICS

Considering the relevant international literature and the sample size used in studies dealing with chronic neck pain (Ruth & Kegerreis 1992, Chinn *et al.* 1994, Lundblad, Elert and Gerdle 1999, Öhman *et al.* 2011, Lundqvist *et al.* 2014, Mohan *et al.* 2016) we assumed a sufficient sample size (n=160). The exact sample number was calculated in order for the method of Analysis of Variance (ANOVA) with two groups of equal population, to identify a standardized effect size (effect size) equal to 0.25 with a power of 80% and a level of statistical significance of 5%. The standardized effect size was defined as follows: Let the measurement tool X and groups A, B and μA, μB be the mean values of X in groups A and B and SD (Standard Deviation) of X in the whole population. The standardized sample size is given by the formula (|μA-μB|)/SD. The calculation was performed with the program G*power version 3.1.9.7* and the necessary sample size was calculated at 128 subjects. However, a dropout rate of 20% was expected, so the sample to be collected will consist of 160 patients (80% will correspond to 128 subjects) who will be equally divided into the two intervention groups.

2.5.1.2. METHOD OF RANDOMIZATION AND BLINDING

The sample will include 160 patients of both sexes, age range 19-70 years. The final study sample will be drawn from an initial preparatory convenience sample from which participants meeting the entry and exclusion criteria will be recruited, who will then form the study sample. The participants will be allocated using the method of simple randomization with an allocation ratio of 1:1, i.e. in two equal groups of 80 people, each.

The randomization of patients to the intervention group and the acupuncture group will be performed with the help of a random number generator created in Stata software with the help of the “randomizer” package, which through the principles of binomial distribution randomly assigns to each participant their participation in either the intervention group or the control group. In this way each participant will be placed in one of two groups at the start of the study and will remain in the same group for the duration of the study. The ratio of subjects between the two groups will be maintained at 1:1 throughout the study.

This study is a single blind clinical trial. Despite the fact that the intervention is perceived both by the researcher applying the treatment protocols and by the participants, all evaluations of the effectiveness of the treatment interventions will be carried out by a third independent assessor who, although belonging to the research team of the study, does not know the type of intervention to be applied to each patient as well as to allocate patients to the different treatment intervention groups (Kang, 2013, Opara *et al.*, 2013).

2.5.1.3. CONDUCT OF RESEARCH - STATEMENT OF CONSENT

The technique of ATM of the Feldenkrais method will be applied in a specially designed space at the Musculoskeletal Physiotherapy Research Laboratory of the University of West Attica (UNIWA), while the acupuncture treatments as well as the assessment measurements for both interventions will be carried out in the clinic pain of the 1st Anesthesiology Clinic of the Aretaeio Hospital. All prospective patients should have a referral from their treating physician certifying a diagnosis of non-specific chronic neck pain. Before the start of the sessions, a written statement of consent will be given that they agree to participate in the research and also that they can stop at any time they wish, in accordance with the regulation of the European Union (2016/679) for the protection of personal data and the rules of medical confidentiality of the Ethics and Ethics Committee of the UNIWA.

2.5.1.4. SAMPLING

The sampling of the study will follow the following steps. Starting on July 25, 2022 and until the required number of people set according to the protocol is

completed, the doctors of the pain clinic of the 1st Anesthesiology Clinic of the Aretaeio hospital, to all patients who will come to the outpatient clinics and will be diagnosed with non- specific neck pain, will assess the exclusion criteria in order to determine the likelihood that patients can participate in the study. The patient will be assessed based on their diagnosis and exclusion criteria in order to participate in the study.

2.5.1.5. INCLUSION CRITERIA

The selection of the sample will be based on the criteria listed in the following table (Table 1).

Table 1. Patient entry criteria

1. **Diagnosis of chronic non-specific neck pain**
2. **The duration of the symptoms must be at least three months before the initial assessment and their participation in the study.**
3. **Presence of reported symptoms of non-radicular etiology in the shoulder or upper extremity.**
4. **Age range 19-70 years.**

2.5.1.6 EXCLUSION CRITERIA

Initially, a clinical examination-diagnosis of chronic non-specific neck pain will be carried out by the attending physician and then, after exclusion of cases that do not fall into the above category or meet at least one of the exclusion criteria listed in the following table (Table 2), the remaining will complete the consent form. Chronic non-specific neck pain refers to pain that is not due to a specific pathology or anatomical abnormalities. Therefore, the diagnosis will result from the exclusion of an identified or serious condition. The symptoms resemble those of Whiplash Associated Disorders (WAD) grades I and II, with the difference that the latter result from a traumatic event (Tsakitzidis *et al.* 2013). It should be noted that Table 2 also lists situations that constitute "red flags".

Table 2. Patient exclusion criteria

1. History of surgical intervention in the cervical spine (Dibai - Fihlo *et al.* 2017)
2. Patients with a history of neck fracture or injury (Campa - Moran *et al.* 2015, Dibai - Fihlo *et al.* 2017) in the last year
3. Head, face or neck surgery (Dibai - Fihlo *et al.* 2017)
4. Active cervical hernia with radicular symptoms or severe degenerative diseases in the cervical spine (Dibai - Fihlo *et al.* 2017)
5. Systemic diseases (diagnosed rheumatic, metabolic and immunological diseases), (Edward & Knowles 2003, Wilke *et al.* 2014, Campa-Moran *et al.* 2015, Cerezo - Téllez *et al.* 2016 Dibai-Fihlo *et al.* 2017, Cerezo - Téllez *et al.* 2018)
6. Myelopathy with severe disc or bone damage (Ma *et al.*, 2010, Campa - Moran *et al.* 2015)
7. Cervical radiculitis/radiculopathy (Ma *et al.* 2010, Wilke *et al.* 2014, Campa - Moran *et al.* 2015)
8. Arterial dysfunction (Kerry *et al.* 2008)
9. Neoplasms active during the last five years
10. Lymphadenopathy (Tsakitzidis *et al.* 2013)
11. History of inflammatory arthritis (Tsakitzidis *et al.* 2013)
12. Diagnosed psychiatric illness (Wilke *et al.* 2014, Cerezo - Téllez *et al.* 2016, Cerezo - Téllez *et al.* 2018)
13. Severe neurological disorder (Edward & Knowles 2003, Wilke *et al.* 2014) or mental retardation (Ma *et al.* 2010)
14. Signs, symptoms or history of oral pain and temporomandibular disorders based on the Research Diagnostic Criteria of Temporomandibular Disorders - RDC/TMD (Campa - Moran *et al.* 2015)
15. Fibromyalgia syndrome diagnosed (Ma *et al.* 2010, Wilke *et al.* 2014, Cerezo - Téllez *et al.* 2016, Cerezo - Téllez *et al.* 2018)
16. Infection or inflammatory swelling in the treated area
17. Skin damage (Edwards & Knowles 2003) or wounds in the puncture area

(Cerezo - Téllez *et al.* 2016, Cerezo - Téllez *et al.* 2018)
18. Systemic intake of drugs that may affect the patient's judgment, (e.g. neuromodulators, antidepressants)
19. Taking systemic treatment for the same problem (Wilke *et al.* 2014) up to three months before the study
20. Pregnancy (Cerezo - Téllez *et al.* 2016, Cerezo - Téllez *et al.* 2018)
21. Previous adverse reaction to acupuncture (Edwards & Knowles 2003)
22. Metal allergy (Cerezo - Téllez *et al.* 2016, Cerezo - Téllez *et al.* 2018)
23. Fear of needles (Edwards & Knowles 2003, Campa-Moran *et al.* 2015, Cerezo-Téllez *et al.* 2016, Cerezo-Téllez *et al.* 2018)
24. Inability to express speech and writing in the Greek language

Participants will then complete the questionnaires and scales. Those who agreed to undergo the interventions will first fill out the demographic characteristics form.

2.5.1.7. PERSONAL DATA AND DEMOGRAPHIC CHARACTERISTICS

The personal data that will be collected from each participant is kept anonymous. At no stage of data collection will any personal information that can be used to identify the participant be requested, so as to protect their personal data inviolably. The above will be achieved with the help of pseudonymization and generalization of information that could link a pseudonym with some exclusive characteristic. For example, if the subject recorded as "Respondent 1" is 37 years old, their age is not recorded, but their age group (35-40). The procedure will be performed by a biostatistician, partner of the Musculoskeletal Physiotherapy Laboratory. In addition, the technique of file encryption will be followed using VeraCrypt Containers (Bursać, Vulović & Milosavljević 2017), i.e. the data will be placed inside a virtual disk file that with the use of "encryption keys" and the algorithm AES-256 will be converted into an unintelligible format so that they cannot be read by researchers, only by the owner of the encryption keys (biostatistician) (Loukas, 2017), protecting them during computer operation, even when they are not in use. The computer that will be used to store and process the

data will be provided with a password, an encrypted hard disk to protect data at rest, from anti-electronic threat software, which will be isolated in the Musculoskeletal Physiotherapy Laboratory and will not have access to the internet. This data will be stored on a computer that has been assigned a password known only to the researchers. They will remain confidential throughout the interventions and after five years the RAM and hard drive of the computer containing all the material and/or information collected from the research will be destroyed, exposing them to microwaves and causing them to wear naturally (e.g., drill holes). All physical records that have been collected (e.g., questionnaires) will be destroyed in a special document shredder.

The demographic characteristics form includes information regarding the participant's gender, age range, body measurements (weight, height), educational level, employment status, and field of employment. In addition, it contains information on marital status, whether neck pain is diagnosed, duration of symptoms, and whether or not surgery has been performed on the head, face, or neck.

2.6. INTERVENTION PROGRAM

2.6.1. STUDY DESIGN

In the proposed doctoral thesis, the ATM technique and biomedical acupuncture protocol in combination with stretching will be applied in patients with chronic neck pain. Primary measures will be the sensation of pain and secondary measures will be the range of motion (ROM) of flexion, flexion-extension and side-flexion of the cervical spine as well as the sense of its position (kinesthesia), the endurance of the deep flexor muscles of the cervical spine, the respiratory function, the overall benefit perceived by the patient, the intensity as well as the sensory, emotional and evaluative dimensions of the pain, the functional capacity of the neck, the recording of anxiety and depression, the fear of movement or re-injury, the quality of life, the perception of fear and the attempt to avoid pain in relation to physical and work activities, the degree of destructive views about pain and the compliance rate. Measurements will be performed before the start

(evaluation phase) as well as at the completion of the therapeutic interventions at five weeks, for both group A (ATM) and group B (A-S).

2.6.1.1. CLASSIFICATION OF PATIENTS INTO SUBGROUPS WITH COMMON CLINICAL CHARACTERISTICS

The smaller effects observed in the systematic review studies for musculoskeletal pain conditions may be due to the heterogeneity of the conditions and their subsequent differentiation. This case raises the question of the merits or otherwise of the subgroup and its subsequent aid in identifying the most effective treatment for each of them. For chronic neck pain, there have been few clinical studies—and all of them involving WADs—investigating subgroup effects (Sterling *et al.* 2019). On the occasion of the above, in this doctoral thesis, an attempt will be made retrospectively to classify the patients who show chronic non-specific neck pain into subgroups with common clinical characteristics with the aim of investigating this in improving the therapeutic effect. In other words, subgroup analyzes will be performed after the completion of the clinical trial, following the main statistical analyses.

To achieve the above, some elements from the international literature were identified. The study by Boyles *et al.* (2010) reported a mean difference between patients in the duration of neck pain of 1166 days (Boyles *et al.* 2010). The high differences raise the concern regarding the response to the interventions of patients who may be in a different stage -subacute, chronic-, and present differences in the factors that affect the specific condition such as respiratory and muscle function, proprioception as well as the function of the thoracic spine. Also, chronic non-specific neck pain, as mentioned in the exclusion criteria, is a consequence of conditions that do not involve underlying serious pathologies. However, its etiology may vary and possibly each of them may affect the interventions in a different way, depending on its pathophysiological background. According to the above, the classification will be based on the duration of the symptoms, as well as the exact etiology of the chronic non-specific neck pain (e.g. MTrPs in the upper part of the trapezius) as derived from its diagnosis.

2.6.1.2. INTERVENTION GROUPS

In group A (ATM), IG, FM's ATM technique will be applied in group sessions and in group B (A-S), CG, biomedical acupuncture protocol combined with stretching exercises.

2.6.1.2.1. GROUP A-ATM (FM)

ATM will involve a series of structured verbally guided motor activities usually conducted in the form of group lesson sessions. The lessons are based on the developmental sequence and vary in level of difficulty from relatively complex, applied to people with physical impairments to hypercomplex addressed to those with high motor requirements ATM will involve a series of structured verbally guided motor activities usually conducted in the form of group lesson sessions. The lessons are based on the developmental sequence and vary in level of difficulty from relatively complex, applied to people with physical impairments to super complex addressed to those with high motor requirements. The duration of each lesson varies and will vary between 30-60 minutes. In the beginning, simple, comfortable, gentle movements will be performed that will gradually develop into complex ones, with a self-determined manner and rhythm by the trainee. The purpose becomes the teaching of execution rather than the completion of the movement. The improvement of awareness and the organization of the body will be caused through the verbal instructions-orders or questions-problems that will be posed by the educators of the method. The above aims to implement a sequence of movements and focus attention on different parts of the body (internal feedback). A corollary to this is the empathy of basic functions. Each lesson will have a specific request and topic, while it will be organized around a functional activity.

ATM affects muscle tone, reduces tension and unnecessary effort, aiming to improve sensorimotor perception. The latter induces the absolute regulation of movements by the trainees. Among the goals is to increase awareness regarding the mechanics of movements. Through the technique, the suspension of stereotyped movement patterns is attempted, the expansion of movement options, the learning of new movements and the presentation of a new way of composing them. A crucial role for the achievement of the aforementioned is played by the

reduction of mental tension, which is caused by encouraging less effort to be exerted each time during the movement. Correcting incorrect moves goes against the philosophy of the method that supports inquiry learning.

According to the philosophy of FM, the treatment of chronic neck pain requires an approach from the perspective of other components besides the cervical spine. In this light, neck pain can originate in the neck but also from other causes, including inadequate breathing patterns, pelvic tilts, insufficient differentiation of eye or head movements, overuse of the upper extremity musculature. An inseparable relationship is detected between the neck and the temporomandibular joint, i.e. the incorrect position of the former affects the function of the latter and conversely the increased tension in the temporomandibular joint changes the muscle tone of the neck. This category also includes the limited movement of the lumbar spine as well as the injury of the end of the foot that disrupts the smooth functioning of the biokinetic chain (Plastaras *et al.* 2011).

In this protocol ten ATM-sessions will be conducted, which are derived from original courses taught by Moshe Feldenkrais, and each of them will address a specific function within the developmental repertory. In details, the first, "Rolling the fists", will aim at the connection between upper limbs and spine. The second, "Stomach and chest first" will activate the diaphragm. The third, "Hip and Shoulder Integration" is the first approach to shoulder differentiation. The "The Movement of the Eyes Organizes the Movement of the Body" helps control the functional connections between the eyes and neck muscles. The "Skewering the spine in the chest" will promote the movement of the spinal chain and is a continuation of the logical choice of "Rolling the fists" with the difference that it aims at the greater range of activation of the central point of the body, connecting the trunk with the upper limbs. The «On the back; twisting the spine with the head fixed» will improve turning by changing the relationship between the proximal -below the A7 vertebra- and distal -cervical spine- parts of the spine. The "A clock in front of the face" will enhance the shoulder-head and spine differentiation. The "Breathing (To weld by breathing)" will increase the volume and flexibility of the rib cage. The «Edges of the feet» will help connect the ankle joints to the hip joints and through them to the

spine and head. Finally, the "On the side, the sternum becoming flexible" will mobilize the sternum in order to improve the turn and extension of the neck. The above lessons have been translated and modified by the main researcher following a specific format as a methodological aid for their reading and understanding.

The ATM technique will be implemented either at the Musculoskeletal Physiotherapy Laboratory of UNIWA, by a physiotherapist specialized in the method with at least five years of experience, for five weeks, two sessions lasting 50 minutes each, per week.

On the remaining days, home exercises will be given to the patients in the form of printed illustrated instructions for their correct execution.

The present study investigates the effect of the ATM technique in the form of group sessions, in a group of patients as intended.

Below is a summary table of the ATM courses in the order they will be held (Table 3).

Table 3. Awareness Through Movement (ATM) Lessons

1º: Rolling the fists **Source: ATM Lesson from Alexander Yanai #68 (Feldenkrais 1995a)**
2º: Stomach and chest first **Source: ATM Lesson from Alexander Yanai #35 (Feldenkrais 1995b)**
3º: Hip and Shoulder Integration **Source: San Francisco Evening Class, Volume 1, Lesson 7 (San Francisco Evening Class 1980)**
4º: The Movement of the Eyes Organizes the Movement of the Body **Source: Lesson 10 from ATM Book (Feldenkrais 1990)**
5º: Skewering the spine in the chest **Source: ATM Lesson from Alexander Yanai Lesson #308 (Feldenkrais 2000)**
6º: On the back; twisting the spine with the head fixed **Source: ATM Lesson from Alexander Yanai #110 (Feldenkrais 1995c)**
7º: A clock in front of the face **Source: ATM Lessons from Alexander Yanai #82 (Feldenkrais 1995d)**
8º: Breathing (To weld by breathing) **Source: ATM Lesson from Alexander Yanai #179 (Feldenkrais 1997a)**
9º: Edges of the feet **Source: ATM Lesson from Alexander Yanai #433 (Feldenkrais, 2001)**
10º: On the side, the sternum becoming flexible **Source: ATM Lesson from Alexander Yanai #217 (Feldenkrais 1997b)**

2.6.1.2.2. GROUP B-AS

The acupuncture-stretching protocol will be performed in ten sessions, two per week, of 40 minutes each, which will include the insertion of a sterile disposable (DongBang Acupuncture, Inc., Korea) into standardized as possible appropriate local, regional and homeostatic general points that will modify the behavior of the pain in the area of the Cervical Spine. Local sites include the MTrPs in the upper part of the trapezius muscle (Ma *et al.* 2010, Campa-Moran *et al.* 2015, Cerezo-Téllez *et al.* 2016, Cerezo-Téllez *et al.* 2018) and the levator scapula muscle (Moran *et al.*, 2015, Cerezo-Téllez *et al.* 2016, Cerezo-Téllez *et al.* 2018). Also, the Gallbladder is included 20/GB 20 (Gallbladder 20/GB 20), Urinary Bladder 43/BL 43 (Bladder 43/BL 43) (Wilke *et al.*, 2014). Paravertebral points belong to the regional ones C1-C5 (both) in the Cervical Spine (Huato Jiaji points), BL 10 (Wilke *et al.*, 2014), GV 15 (Karavis, 2011), and finally in general the TW 5, LJ 4, SI 3 (Karavis, 2011, Wilke *et al.* 2014) και GV 14 (Karavis, 2011). The protocol points are listed in Table 4.

Table 4. Biomedical acupuncture protocol points

Local	Regional	General
SI 14 MTrP	Huato Jiaji C5	TW 5
GB 21 MTrP	BL 10	LJ 4
GB 20	GV 14	
BL 43		

Acupuncture will be performed for 25 minutes by a certified acupuncturist with years of experience. After the needle is removed, compression will be applied to the injection sites for 40 seconds to prevent any microbleeding (Campa-Moran *et al.*, 2015). Potential events, with the exception of dermatitis, will be managed in accordance with the "Management of Adverse Reactions to Acupuncture and Dry Needling" section of the Guide to Safe Acupuncture and Use of dry needling of the World Confederation of Physical Therapy (WCPT) and the special subgroup

dealing with acupuncture (International Acupuncture Association of Physical Therapists – IAAPT). In the event of dermatitis after the application of acupuncture, a wet towel or cloth can be applied to the affected area, followed by a corticosteroid cream, gel or ointment or a cream or ointment containing calcineurin inhibitors. The affected skin can be subjected to phototherapy, i.e., controlled amounts of natural or artificial light (Dermatitis,2020). If symptoms persist, the patient should be referred to their treating physician. It is pointed out that the side effects result from improper sterilization and use of the needles (Sfara, 2013). White (2004) estimated the risk of a serious adverse event to be 0.05/10.000 treatments and 0.55/10.000 patients.

The 15-minute stretches will also follow a pre-planned application and explanation process and will be as systematic as possible for patients. They will be performed at home after prior instruction by the same physical therapist. The following muscles will be applied: upper trapezius, levator scapulae, scalenes, extensors of the ACL (splenoid, spinous, semispinalis, longus cephalic and cervical, iliolateral cervical, multifidus and subscapularis), and sternocleidomastoid. In detail, lateral flexion and counterrotation of the head will be performed for the upper part of the trapezius and the anterior scalene, lateral flexion and corresponding rotation for the levator scapulae, and flexion for the extensors of the Cervical Spine. Häkinnen, *et al.,* proposed the following protocol: the duration of each stretch is set to 30 seconds and will be repeated three times (Häkkinen, *et al.*, 2007). There will be a one-minute rest between stretches. At the same time, it will be performed five times, lasting five seconds, approaching the head with the aim of stretching the posterior muscles. There will be a ten second break between attempts. The sessions will take place in the pain clinic of the 1st Anesthesiology Clinic of the Aretaeio Hospital - a special space for these treatments.

2.6.2. MEASURING TOOLS

Field tests (assessment markers) were selected based on their validity, reliability, ease of application and clinical economy.

2.6.2.1. PRIMARY OUTCOME MEASURE

An algometer (Commander Algometer, JTECH Medical, Midvale, Utah) will be used in the primary measurement regarding the assessment of pain sensation (physiological measurement). This model is a handheld algometer with four different heads with surface of 0.5 cm^2, 1 cm^2, a flat pad and a fingertip adapter. The maximum input force reaches 111 N while the wireless radio frequency (RF) reaches 2.4 GHz (Commander Echo n.d.).

The selected model (Commander Algometer, JTECH Medical, Midvale, Utah) has been used to detect the pressure that causes painful symptoms (threshold) when performing the neurodynamic test of the median nerve between patients with unspecified neck pain and asymptomatic patients. Measurements will be taken from the middle part of the upper two degrees of the trapezius muscles. The head to be used has an area of one square centimeter (1cm^2) and the unit of measurement for the threshold value is kilogram per square centimeter (kg/cm^2). For the reliability of the results, the measurements will be repeated three times and the average was calculated from the resulting values. Demographic data and measurement results will be recorded as mean ± standard deviation and compared between the control group and the unspecified pain group using the Mann-Whitney U test. According to the results between the two groups, a significant reduction in the pressure threshold will be detected in the intervention group compared to the control group ($p<0.001$) (Yılmaz, Taş & Yılmaz 2017).

In this PhD thesis, the pain recording will be performed at specific points such as the upper part of the trapezius muscle and the subspinal region, as the pressure algometer has shown high reliability when applied to the upper part of the trapezius muscle (ICC: 0.85-0.86) and in the posterior region (ICC: 0.84-0.93) in patients with chronic non-specific neck pain (Pérez-Martinez-Casero et al., 2020). The measurement in the posterior region will be performed at the mastoid process and at the BL 10 point, which is located on the horizontal line that passes between the spinous processes of the C1 and C2 vertebrae and the oblique line that passes through the outer border of the upper part of the trapezius muscle . It is exactly 1 centimeter on either side of the vertical axis of the body, which passes through the spinous processes of the C1 and C2 vertebrae. In the upper part of

the trapezius muscle, the measurement point is between the midline and the lateral border of the acromion (Wang-Price et al., 2019). In addition, measurements will be made at the zygopophyseal joint between C5-C6 intervertebral space (1/2 cun), at the tibialis anterior muscle (Stomach 36/ST 36), at the middle part of the deltoid muscle (1-2 cm below the acromion) as well as in the levator scapula muscle (2 cm above its epiphysis, at the upper medial angle of the scapula) (Wang-Price et al., 2019). Patients will be placed in a prone position (Fischer, 1987) for all measurements. At each aforementioned point, three measurements will be taken with the possibility of a 30-second break between measurements (Pelfort et al., 2015). The first measurement is considered tentative and is rejected. The average of the two measurements is then calculated and recorded as the final value. The force applied for the measurements is perpendicular to the body surface and the rate of pressure increase constant at 1 kg/cm2 per second (Reeves et al., 1986; Koo et al., 2013), because if it is not constant it increases the possibility of incorrect measurement. The head to be used is that of one square centimeter (1 cm^2) and the unit of measurement for the threshold value is the kilogram per square centimeter (kg/cm^2).

2.6.2.2. SECONDARY OUTCOME MEASURES

2.6.2.2.1. RANGE OF MOTION AND MOTION SENSOR

Secondary measurements include range of motion (ROM) of flexion, flexion-extension and lateral flexion of the cervical spine as well as the sense of its position (kinesthesia). To record them, the 3D inertial motion MOOVER sensor of the company SENSOR medica Technology in Motion, dimensions 36×32×12mm and weight 15gr, will be used, which evaluates movements, accelerations and turns. It has a 16bit resolution, automatic calibration, frequency up to 1000Hz, battery life of six hours and the connection is achieved via Bluetooth 3.0.

It is a valuable tool for prevention and rehabilitation, because the level of the patient's initial picture is recorded and then throughout the treatment the improvement is monitored. The sensor allows the goniometric evaluation of the joints as well as the measurement of the energy and strength of the lower limbs (jump test). Consequently, it assesses the tilt as well as the rotation of the pelvis

during walking or running. Finally, it evaluates with the use of a baropodometric/stabilometric platform the oscillation of the center of gravity of the body and the subsequent oscillation of the head and/or trunk (Sensor medica 2020).

2.6.2.2.2. PRESSURE BIOREACTION STABILIZER

The endurance of the deep flexor muscles of the spine will be assessed with a Chattanooga Stabilizer Biofeedback Pressure. The stabilizer allows physical movements and especially those concerning the spine during exercise. The changing pressure will be recorded in an air-filled pressure cell, which is connected to a combined guide and plier. It is a device used for joint protection and stabilization exercises that contribute to the treatment and prevention of pain in the cervical spine or lumbar spine, while it also provides biofeedback to physical movements, reducing pain in these areas. The proportional pressure range is between 0 mmHg-200 mmHg with an accuracy of +/−3mmHz (Chattanooga, 2020). The efficiency index is calculated as the quotient where the numerator records the pressure increase in the chamber and the denominator the number of repetitions. The maximum applied pressure sustained for a period of ten seconds is defined as the degree of activation (Magee 2018).

2.6.2.2.3. SPIROMETER

For the evaluation of the respiratory function, a portable spirometer of the MIR company (MIR Spirodoc) with dimensions of the central unit 101x48x16mm and weight 99g and 46x47x24mm and 17g respectively for the removable head-turbine will be used. It has an LCD touch screen, a rechargeable battery with a 30-hour reserve measurement, a built-in three-axis motion recorder (triaxial sensor-3D Oximeter®), while it can be connected to the computer either with USB 2.0 or Bluetooth® 2.1. It is indicated for applications in the field of rehabilitation, telemedicine and clinical research (Medical International Research 2020).

2.6.2.2.4. GLOBAL PERCEIVED EFFECT (GPE)

The scale with the overall benefit perceived by the patient (GPE) gives the opportunity to the patients, through certain questions, to evaluate themselves the recovery and the improvement or deterioration of their health. More specifically, it consists of simple and clear questions, which cover several areas, so that there is

the possibility of a more general conclusion about the course of rehabilitation (Kamper et. al 2010). This scale is often used in musculoskeletal conditions, especially when they are chronic, such as chronic neck pain (Meisingset et al. 2018). A model of the GPE scale for chronic neck pain includes five main domains: pain symptoms, biomechanical performance, daily activities, self-care, and the need for other treatments (Evans et al. 2014). Despite the ease of application of the GPE, it is a challenge for patients to accurately remember the state in which they were most recently and not to confuse the current state with the corresponding past state (Kamper et al. 2010).

2.6.2.2.5. SHORT QUESTIONNAIRE FORM McGILL (SFMPQ)

Pain will also be assessed subjectively with the SFMPQ questionnaire presented by Melzack in 1987 and includes its intensity as well as its sensorial, emotional and evaluative dimensions (Melzack 1987). It consists of 15 adjectives describing the sensation of pain -11 sensorial and four emotional, a ten-point Visual Analogue Scale (VAS) and a scale describing the present intensity of pain (0=No pain, 1=Mild, 2 =Annoying, 3=Painful, 4=Horrible, 5=Unbearable). The patient self-rates them according to the level of intensity with the help of a four-point scale, where 0=No pain, 1=Mild, 2=Moderate and 3=Severe. The total score amounts to 45 points -33 for the sensorial subscale, 12 for the emotional subscale, 10 for the VAS and 5 for the present pain intensity- (Neurotoolkit 2020). The short form of the questionnaire was translated and validated to the Greek population in 2000 by Georgoudis, Watson and Oldham (the GREEK-SMFPQ/the GR-SFMPQ). Furthermore, the SFMPQ is comprehensible and can be completed by people of different educational levels (even primary school graduates). Finally, it is a tool for multidimensional assessment of pain in patients with chronic musculoskeletal problems (the research sample in the Greek population consisted of patients experiencing chronic pain with spinal and osteoarthritic conditions) (Georgoudis, Watson & Oldham, 2000).

2.6.2.2.6 NECK DISABILITY INDEX (NDI)

Neck functional capacity will be assessed with the self-reported NDI. The NDI captures disability/inability to perform daily activities due to neck pain. It consists of ten items, eight of which relate to various activities (personal care,

lifting, driving, work, sleep, concentration, reading, entertainment) and two to pain in terms of intensity parameters and headache. Each item corresponds to six answers from which the participant must choose only one, the one that best represents his current situation. The lowest score for each item is zero which is assigned as no pain and no functional limitation and the maximum five which refers to the worst pain and maximum limitation. It is therefore understandable that the total score ranges from zero to fifty (Trouli et al. 2008), with values 0-4 (0%-8%) corresponding to no disability, 5-14 (10%-28%) to mild disability, 15-24 (30%-48%) to moderate disability, 25-34 (50%-68%) to severe disability and 35-50 (70%-100%) to total disability (Magee 2018).

The scale was translated and validated to the Greek population by Trouli et al. (2008) and proved to be a reliable, valid and useful tool for research and clinical environment of Greek primary health care.

2.6.2.2.7. HOSPITAL ANXIETY & DEPRESSION SCALE (HADs)

To record anxiety and depression, the HADs scale will be used. It is a self-report scale of 14 items, which are classified on a four-point scale (Likert scale) numbered 0-3. It has two subscales; HADs_anxiety and HADs_depression, each of which contains seven items. The total score ranges from 0-21 for each subscale (Michopoulos et al., 2008), where values of 0-7 correspond to normal depression/anxiety, 8-10 to borderline abnormal, and 11-21 to abnormal (Svri 2020). It is a reliable, valid scale for recording anxiety and depression and has been validated to the Greek population (Michopoulos et al. 2008).

2.6.2.2.8. TAMPA SCALE KINESIOPHOBIA (TSK_GR)

Fear of movement or re-injury will be captured with the TSK_GR which is a 17-item questionnaire with a score of 17-68. In 2005, it was validated by Georgoudis, Katsoulakis and Kanellou to the Greek population after examining 70 patients with chronic low back pain. Four values are assigned to each of the 17 questions; 1=Strongly disagree, 2=Disagree to some extent, 3=Agree to some extent, 4=Strongly agree, and the total score is obtained after reversing questions 4, 8, 12 and 16. If the latter amounts to 37 or less then it is associated with a low fear of movement, while on the contrary 37 or more with increased fear of

movement. The Greek version was shown to have validity and reliability. The internal consistency attributed to Cronbach's coefficient was 0.74 (a=0.74), a value considered satisfactory and even appeared increased (a=0.83) when questions 4, 8, 12 and 16 were not included (Georgoudis, Katsoulakis & Kanellou 2005).

2.6.2.2.9. SF- 12 HEALTH SURVEY (SF-12)

Quality of life will be assessed using the SF-12 questionnaire, which has been validated to the Greek population. The SF-12 is the short, alternative form of the SF-36 and assesses with the use of two items the parameters physical functioning (PF), physical and emotional role (role physical/RP, role emotional/RE) and mental health (MH) (Kontodimopoulos et al. 2007). The score is 56,577 and 60,757 for physical role and mental health respectively (OrthoToolKit 2020). The parameters bodily pain (BP), general health (GH), social functioning (SF) and vitality (VT) are controlled by one object each. It consists of two factors of conceptual structure; PCS -correlated with PF, RP, BP and GH- and Mental Impact Index (mental component summary/MCS) -correlated more with SF, RE and MH-. It is noted that the VT item has a slightly higher correlation with the PCS score (Kontodimopoulos et al. 2007).

2.6.2.2.10. FEAR- AVOIDANCE BELIEFS QUESTIONNAIRE (FABQ_GR)

To record the perception of fear and the effort to avoid pain in relation to physical and work activities, the Greek version of the FABQ questionnaire (FABQ_GR) will be chosen, which was validated by Georgoudis, Kanellos and Katsoulakis in 2005. The FABQ is a self-referential questionnaire consisting of 16 questions, each of which is scored from zero to six. Therefore, the total score is 96 points. Higher scores correspond to strong perceptions of fearing and avoiding pain.

Consequently, it consists of two subscales; the FABQ_physical composed of four questions and assessing the aforementioned parameters in relation to physical activities and the FABQ_work, of seven questions on the same perceptions at work, with scores ranging between 0-24 and 0-42 respectively. The remaining five questions aim to distract the patient. Both models, as demonstrated by a clinical study conducted in the Greek population -70 patients with chronic low

back pain-, had satisfactory internal validity (FABQ_work Cronbach's a=0.86, FABQ_physical Cronbach's a=0.72).

2.6.2.2.11. PAIN CATASTOPHIZING SCALE (PCS)

To measure the degree of catastrophizing about pain, the PCS scale will be used, which is a 13-item instrument derived from the definitions of catastrophizing analyzed in the literature and from items from the catastrophizing subscale of the Coping Strategies Questionnaire (CSQ). Participants will be asked to recall past painful experiences and rate each of 13 thoughts or feelings on a five-point scale, where zero (0) corresponds to not at all and four (4) to constantly/all the time. Furthermore, it has been shown to have adequate to excellent internal consistency and requires a reading level of about grade six, which corresponds to the level of a 6-6.5-year-old child. It consists of three aspects of catastrophizing; Rumination (R) consisting of four questions, Magnification (M) consisting of three questions and Helplessness (H) consisting of six questions. The total score is calculated from the sum of the individual 13 question scores and ranges from zero to 52 (Sullivan 2009).

The scale has been validated to the Greek population by Chatzidimitriou and colleagues (2006).

2.7. COMPLIANCE RATE

In addition to the aforementioned, the survey will also record the compliance rate of the participants in the two interventions. This will be implemented in the following way: in each session each participant will receive a paper form to fill in on which the exercises to be performed at home will be written and next to them an Y (YES) or N (NO) will be marked depending on whether they have been performed or not. Each completed form will be returned to the physical therapist. When the cycle of sessions is completed, the degree of compliance of all participants will be assessed by the evaluator.

2.8. COMPLAINT FORM

Before the start of the interventions, each participant will be given a complaint form to submit their possible complaints and record the problems they

may have encountered and/or their observations regarding the provided interventions, the overall design and organization of the research, the scientific group or anything else they deem worth mentioning. The form will be returned to the principal investigator of the program after the sessions are completed. In addition, each participant will be given the e-mail address of the main researcher of the program so that communication between participants and the main researcher is possible at any time if the need arises.

2.9. PROCEDURE

Initially, the prospective participants who will come from the structures mentioned in the section "Conducting research - Declaration of consent" will send through their electronic mail or by hand their medical diagnosis. The latter, combined with the exclusion criteria set, will be the way to sort the appropriate population. Participants will complete their consent form and demographic information. A full musculoskeletal assessment by an experienced physical therapist trained in the identification of myofascial pain trigger points (MTrPs) will be required at the start of the A-S group protocol. The determination of each MTrP will be achieved by palpation of the muscles under examination - upper trapezius and levator scapulae -, based on the criteria of Travell and Simons (1992). The points will be marked with an indelible ink and recorded on a body chart. The skin will be cleaned with alcohol before the start of the intervention. The ATM technique requires no preparation.

During the intervention period (five weeks) the exact protocol will be followed, as analyzed in the corresponding subsections "Group A-ATM (FM)" and "Group B-A-S". Acupuncture sessions will take place in the Pain Clinic of the Aretaeio hospital and will be carried out at ambient temperature (25°C) as the reduced temperature causes vasoconstriction making it difficult to apply acupuncture. The treatment area will be quiet, sunny and clean. The two interventions will take place in the morning and afternoon, from 8.30 am to 6.30 pm.

Measurements will be carried out at the time points before the start of the intervention, after completion and at the follow-up at four months. In detail, PPT, ROM of flexion-extension, rotation and side flexion and neck position sense,

respiratory function and flexor muscle strength will be recorded while patients will complete all seven questionnaires. From the total sample number, the patients participating in the follow-up will be calculated and therefore the cumulative dropout rate will be derived, which will be allocated to the two groups. Those who do not successfully complete treatment will be asked about the reasons that contributed to this. Finally, adverse effects from the application and/or ATM will be recorded.

2.10. INTENTION-TO-TREAT ANALYSIS

In the first year, an exploratory data analysis (EDA) will be carried out to evaluate the distribution of the data obtained from each variable and the existence of missing values. Data visualization will be carried out during the EDA, identifying and recording appropriate case-by-case measures of location and dispersion, as well as possible outliers or influential observations (Chatfield, 1986). Normality tests will then be performed (Ghasemi and Zahediasl, 2012) in order to select the appropriate parametric or non-parametric statistical approaches.

The main part of the statistical analysis will assess the existence of statistically significant differences in the outcomes of interest, as described above, before the intervention program, after the intervention program, and at follow-up. Given the nature of the outcomes of interest, appropriate statistical approaches for pairwise comparisons are simple linear retrogression to detect statistically significant results and multiple linear retrogression to assess statistically significant findings in the presence of confounders (Schober and Vetter, 2020). The existence of longitudinal patterns in the data will be assessed using linear mixed effects models (Harrison et al., 2018). Finally, the validity of the retrogression models will be tested and the necessary sensitivity analyzes will be performed.

Comparisons will be made at the conventional level of statistical significance ($\alpha=0.05$) but exploratory analyzes will also be made at the level of statistical significance $\alpha=0.10$. Data management will be performed in Microsoft Excel 2007 software and statistical analysis with STATA v16.0 software.

For the statistical analysis, the data will be collected at three different times: immediately before the start of the interventions (*P1*), immediately after the end (*P2*) and four months after the start of them (*P3*). Therefore, for each measurement

tool two measurements will be assigned (one for the ATM intervention group and one for A-S), which will be performed three times. The purpose was to check the effect of each intervention on each measurement tool, as well as to compare the effects of the interventions for each of them.

For each measurement tool, descriptive statistics and frequencies will be calculated and data will be tested for approximation to normal distribution (Kolmogorov-Smirnov Test). The Kolmogorov-Smirnov test examines the hypothesis:

H_0: *The observations follow a normal distribution*

H_1: *The observations do not follow a normal distribution*

Depending on the result of the check we will continue as follows:

1) The Kolmogorov-Smirnov test does not reject the normal distribution hypothesis.

α) In order to establish the effectiveness of each intervention separately, we will compare the mean values of the measurements per intervention group for the stages (or time points) *P1, P2, P3*. The comparison will be made using the repeated measures ANOVA method. The test performed by repeated measures ANOVA is:

H_0: *There are no statistically significant differences between time periods*

H_1*: There is a statistically significant difference for at least one time period*

Sphericity will be checked with the Mauchly test and if rejected the Greenhouse-Geisser correction will be used. If the method reaches a statistically significant result (at least one of the three mean values is different from the others), we will proceed with a post hoc Bonferroni test to identify between which time periods the intervention produced a statistically significant difference.

β) In order to compare the effectiveness of the two interventions, analysis of variance (ANOVA) will be applied for each time point (*P1, P2, P3*) between the two intervention groups. The test performed by ANOVA is as follows:

H_0: *There are no statistically significant differences between the intervention groups*

H_1*: There is a statistically significant difference between the intervention groups*

For the application of ANOVA, it will be checked if the variances in the two groups are equal with a Levene test (Test of homoscedasticity). If equality of variances is rejected the Welch test for unequal variances will be used.

2) The Kolmogorov-Smirnov test rejects the normal distribution assumption.

α) In order to establish the effectiveness of each intervention separately, we will compare the median values of the measurements per intervention group for the stages (or time points) *P1, P2, P3*. This comparison will be done with the Friedman test. The Friedman test examines the following hypothesis:

H_0: *There are no statistically significant differences between the time periods*

H_1*: There is a statistically significant difference for at least one time period*

If the method reaches a statistically significant result (at least one of the three median values is different from the other two) we will proceed with a post hoc Wilcoxon signed-rank test to identify between which time periods the intervention brought about a statistically significant difference.

β) In order to compare the effectiveness of the two interventions, a Mann-Whitney U test will be applied for each time point (*P1, P2, P3*) between the two intervention groups. The Mann-Whitney U test examines the hypothesis:

H_0: *The distributions of the observations of the two groups are equal*

H_1*: The distributions of the observations of the two groups are not equal*

All tests will be done at the 5% level of statistical significance and data will be analyzed with the IBM Corp. statistical program. Released 2017. IBM SPSS Statistics for Windows, Version 25.0. Armonk, NY: IBM Corp.

2.11. RESULTS

Through the research, the effectiveness or otherwise of the FM method will be highlighted and comparisons will be made between its effect and acupuncture-stretching with regard to specific parameters evaluated at specific times (before and after the completion of the intervention - five weeks). Findings will be drawn for each individual hypothesis of both research questions with the aim of verifying or rejecting them. In detail, sensitivity, ROM, kinesthesia, endurance of the deep neck flexor muscles, respiratory function, intensity and quality of pain, functionality, psychometric characteristics and kinesiophobia will be assessed and contrasted between interventions. After comparing the mean values of the groups in each evaluation for each parameter, it will be established on the first level if the method under consideration had benefits in patients with chronic neck pain and on the second level if it shows statistically significant results compared to the acupuncture- stretching intervention, if non-significant differences are detected between groups or if CG predominates. FM can show a positive effect for certain parameters, so the findings will be presented individually for each of them.

2.12. DISCUSSION

In the discussion the results will be recapitulated, analyzed and related to the existing literature. Each parameter of each research question will be assessed individually and the correlation based on the results obtained with the existing literature listed in the general part will be highlighted. If the hypothesis is verified then it will be compatible with the findings of the studies so far. Otherwise, it is against them. Finally, the above will be interpreted and the reason will be justified.

The aim of each study is to minimize the limitations to draw safer conclusions and then to generalize the results and limitations.

The sample will consist of a wide age and social spectrum, which gives more credibility to the study. The effect of FM on different ages and social groups

with the possible highlighting of its effectiveness increases the power of the method giving the possibility of its application without limitations.

Furthermore, a variety of parameters will be evaluated in a large sample number, providing the possibility of deriving statistically significant results. The examinees constitute a satisfactory amount, larger than that of the majority of studies analyzed in the systematic review.

The design of the study chosen as a 'single-blind' method eliminates systematic error for the observer. Recording the compliance rate is an additional advantage and is not included in most studies.

Finally, limitations include the time-consuming conduct of the intervention group protocol compared to acupuncture.

2.13. CONCLUSIONS-CLINICAL IMPLICATIONS

The results of the measurements will provide a clear picture of how the standardized ATM lessons will be conducted in the form of individual sessions, which is original as they are intended for a group of students-patients. The effect of ATM on a common condition - chronic neck pain - will be established based on a standardized procedure with a randomized controlled trial with a 'blind' assessor (single blind). The acupuncture-stretching combination is used by many researchers and the present study will contribute to highlight the effectiveness of this protocol in the examined condition. Finally, a comparison of the two interventions will be carried out in terms of evaluation parameters (sensitivity, ROM, kinesthesia, endurance of the deep neck flexor muscles, respiratory function, intensity and quality of pain, functionality, psychometric characteristics, kinesiophobia). It should be taken into account that due to the lack of literature the investigation of the effect of FM is largely unknown, while the proper function of the cervical affects the spine as a whole as well as the function of the upper extremity, with the result that the ATM technique is a valuable resource in prescribing exercises for patients.

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