University of West Attica

Health and Care Sciences

Department of Physiotherapy

Date: 22/04/2025

Study Protocol and Statistical Analysis Plan

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

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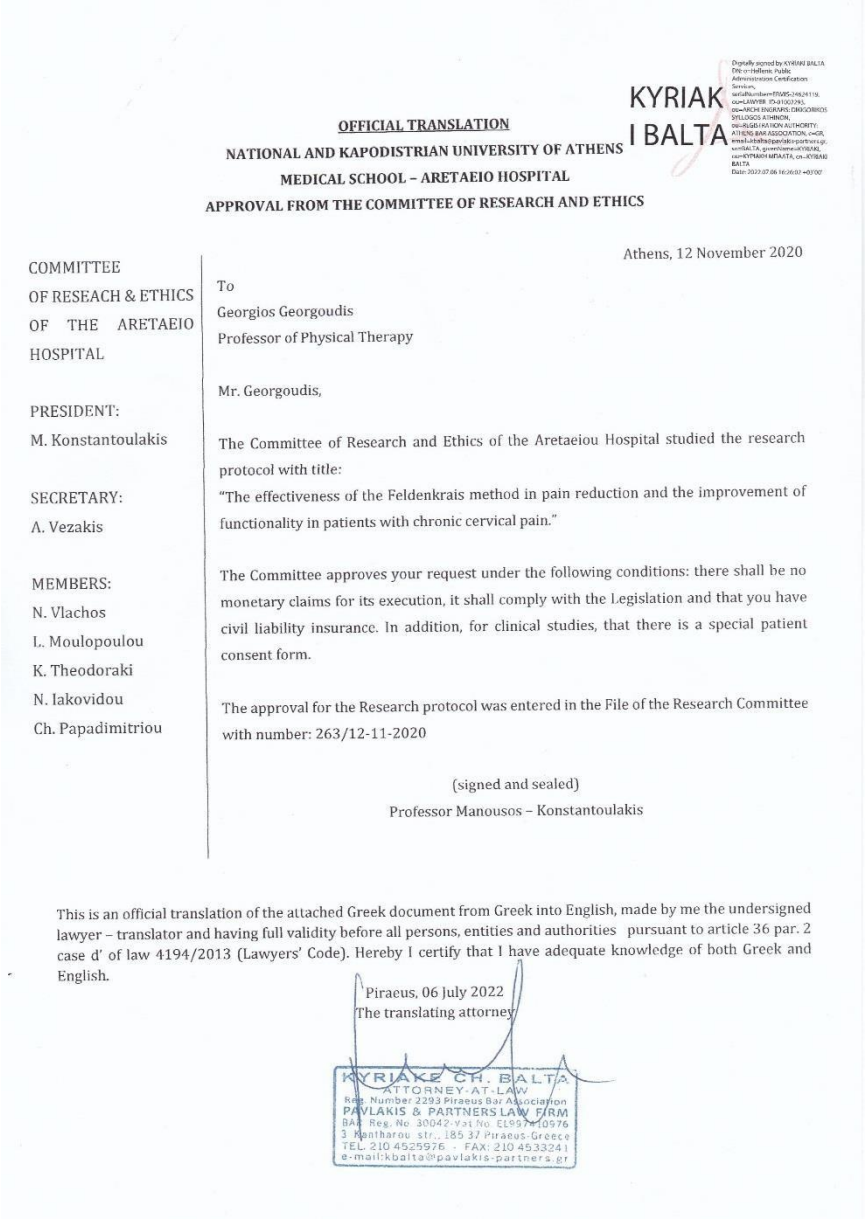
1. INFORMED CONSENT FORM

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 EL99[illegible]0576
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

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 3293 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 psychological parameters in patients with chronic neck pain, both as a single intervention (1st arm) and compared to a protocol of biomedical acupuncture combined with stretching (A-S) (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 A-S.

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 pain sensitivity assessed by the Pain Pressure Threshold (PPT) measured

with the pressure algometer (Commander Algometer) in patients with chronic neck pain (main hypothesis).

- Null hypothesis H_{0A2}: The application of ATM does not affect the cervical range of motion (ROM) recorded with the Moover threedimensional (3D) Inertial Motion 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 the Chattanooga Stabilizer Pressure Biofeedback in patients with chronic pain in the cervical spine (secondary hypothesis).
- Null hypothesis H_{0A4}: The application of ATM does not affect the respiratory function assessed by the portable spirometer (MIR Spirodoc) 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) 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 anxiety and depression captured by the Hospital Anxiety & Depression Scale (HADS) in patients with chronic neck pain (secondary hypothesis).
- Null hypothesis H_{0A8}: The application of ATM does not affect the kinesiophobia as measured by the Tampa Scale Kinesiophobia (TSK_GR) in patients with chronic neck pain (secondary hypothesis).
- Null hypothesis H_{0A9}: The application of ATM does not affect the perception of the fear and the effort to avoid pain in relation to physical and work activities assessed by the Fear Avoidance Beliefs

Questionnaire_Greek version (FABQ_GR) in patients with chronic neck pain (secondary hypothesis).

- Null hypothesis H_{0A10}: The application of ATM does not affect the degree of pain catastrophizing recorded by the Pain Catastrophizing Scale (PCS) in patients with chronic neck pain (secondary hypothesis).
- Null hypothesis H_{0A11}: The application of ATM does not affect the quality of life as measured by the Short Form 12-item Health Survey (SF-12) in patients with chronic neck pain (secondary hypothesis).

- Research question 2: Effectiveness of ATM versus A-S

  - Null hypothesis H_{0B1}: The effect of applying ATM does not differ in reducing the pain sensitivity (PPT) in patients with chronic neck pain from applying A-S (main hypothesis).
  - Null hypothesis H_{0B2}: The effect of the application of ATM does not differ in the improvement of the cervical ROM in patients with chronic neck pain from the application of A-S (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 A-S (secondary hypothesis).
  - Null hypothesis H_{0B4}: The effect of the application of ATM does not differ in the improvement of the respiratory function in patients with chronic neck pain from the application of A-S (secondary hypothesis).
  - Null hypothesis H_{0B5}: The effect of the application of ATM does not differ in the reduction of pain in terms of its intensity and quality in patients with chronic neck pain from the application of A-S (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 A-S (secondary hypothesis).
  - Null hypothesis H_{0B7}: The effect of the application of ATM does not differ in the reduction of anxiety and depression in patients with chronic

pain in the cervical spine from the application of A-S (secondary hypothesis).

- Null hypothesis H_{0B8}: The effect of the application of ATM does not differ from the application of A-S in reducing kinesiophobia in patients with chronic neck pain (secondary hypothesis).
- Null hypothesis H_{0B9}: The effect of the application of ATM does not differ in the improvement of perception of fear and effort to avoid pain in relation to physical and work activities in patients with chronic neck pain from the application of A-S (secondary hypothesis).
- Null hypothesis H_{0B10}: The effect of the application of ATM does not differ from the application of A-S in reducing pain catastrophizing in patients with chronic neck pain (secondary hypothesis).
- Null hypothesis H_{0B11}: The effect of the application of ATM does not differ in the improvement of quality of life in patients with chronic pain in the cervical spine from the application of A-S (secondary hypothesis).

The alternative 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)

  - Alternative hypothesis H_{1A1}: The application of ATM affects the pain sensitivity assessed by the Pain Pressure Threshold (PPT) measured with the pressure algometer in patients with chronic neck pain (main hypothesis).
  - Alternative hypothesis H_{1A2}: The application of ATM affects the range of motion (ROM) recorded with the Moover three-dimensional (3D) Inertial Motion 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 the Chattanooga Stabilizer Pressure Biofeedback in patients with chronic pain in the cervical spine (secondary hypothesis).

- Alternative hypothesis H_{1A4}: The application of ATM affects the respiratory function assessed by the portable spirometer (MIR Spirodoc) 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) in patients with chronic neck pain (secondary hypothesis).
- Alternative hypothesis H_{1A6}: The application of ATM affects the improvement of 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 anxiety and depression captured by the Hospital Anxiety & Depression Scale (HADS) 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).
- Alternative hypothesis H_{1A9}: The application of ATM affects the perception of fear and the effort to avoid pain in relation to physical and work activities recorded with the Fear Avoidance Beliefs Questionnaire_Greek version (FABQ_GR) in patients with chronic neck pain (secondary hypothesis).
- Alternative hypothesis H_{1A10}: The application of ATM affects the pain catastrophizing assessed by the Pain Catastrophizing Scale (PCS) in patients with chronic neck pain (secondary hypothesis).
- Alternative hypothesis H_{1A11}: The application of ATM affects the quality of life captured by the Short Form 12-item Health Survey (SF12) in patients with chronic neck pain (secondary hypothesis).

- Research question 2: Effectiveness of ATM versus A-S

  - Alternative hypothesis H_{1B1}: The effect of applying ATM differs in reducing the pain sensitivity (PPT) in patients with chronic neck pain from applying A-S (main hypothesis).
  - Alternative hypothesis H_{1B2}: The effect of the application of ATM differs in the improvement of ROM in patients with chronic pain in the cervical spine from the application of A-S (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 A-S (secondary hypothesis).
  - Alternative hypothesis H_{1B4}: The effect of applying ATM differs in improving the respiratory function in patients with chronic neck pain from applying A-S (secondary hypothesis).
  - Alternative hypothesis H_{1B5}: The effect of the application of ATM differs in the reduction of pain in terms of its intensity and quality in patients with chronic neck pain from the application of A-S (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 A-S (secondary hypothesis).
  - Alternative hypothesis H_{1B7}: The effect of the application of ATM differs in the reduction of anxiety and depression in patients with chronic pain in the cervical spine from the application of A-S (secondary hypothesis).
  - Alternative hypothesis H_{1B8}: The effect of applying ATM differs in reducing kinesiophobia in patients with chronic neck pain from applying A-S (secondary hypothesis).
  - Alternative hypothesis H_{1B9}: The effect of the application of ATM differs in the reduction of the perception of fear and effort to avoid pain in relation to physical and work activities in patients with chronic neck pain from the application of A-S (secondary hypothesis).

- Alternative hypothesis H_{1B10}: The effect of applying ATM differs in improving pain catastrophizing in patients with chronic neck pain from applying A-S (secondary hypothesis).
- Alternative hypothesis H_{1B11}: The effect of the application of ATM differs in the improvement of the quality of life in patients with chronic pain in the cervical spine from the application of A-S (secondary hypothesis).

2.4. OBJECTIVE GOALS

Objectives of the study are summarized in the investigation of statistically significant differences in the outcomes of interest, i.e. in the measurements for pain sensitivity, intensity and quality (pressure algometer and SFMPQ), functionality (NDI), ROM (Moover 3D Inertial Motion sensor), endurance of deep neck flexor muscles (Chattanooga Stabilizer Pressure Biofeedback), respiratory function (portable spirometer) and psychological parameters (HADS, TSK, FABQ, PCS, SF-12). Differences in the outcomes of interest may arise:

a) between the start time (baseline) and the end time of the study within the A-ATM group (A-ATM group at baseline versus A-ATM group after the intervention).

b) between the compared groups of the clinical trial {group A ATM (Intervention Group) versus group B A-S (Active Control Group)}, both at the beginning of the study, as well as after the intervention.

2.5. MATERIAL AND METHOD

2.5.1. SAMPLE

2.5.1.1. SAMPLE CHARACTERISTICS

During the initial calculation of the sample number, the number of the participants was determined, with purpose, the method of Analysis of Variance (ANOVA) in two groups of equal population, to identify a standardized effect size equal to 0.25 with a power of 80% and a level of statistical significance of 5%. The standardized effect size is 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. SD is the Standard Deviation of X in the whole population. The effect 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 126 subjects. According to the relevant literature, similar standardized sample sizes have been used in two studies dealing with chronic neck pain (Lundblad *et al*., 1999; Malmgren-Olsson *et al*., 2009). Moreover, a dropout rate of 20% was expected, so a final number of around 152 patients is realistic for this study.

2.5.1.2. METHOD OF RANDOMIZATION AND BLINDING

The sample will include 152 patients of both sexes and age range 19-70 years. Participants will be collected using the simple random sampling method and these meeting the inclusion and exclusion criteria will be recruited and will 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 76 people, each.

The randomization of patients to the A ATM group and the B A-S group will be performed with the help of a random number generator created in Stata software with the help of the “randomizer” package. The “randomizer” package through the principles of binomial distribution, randomly assigns to each participant their participation in either the intervention group or the active 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. The intervention will be perceived by the principal researcher, who will apply the treatment protocol in the intervention group (A ATM), the physiotherapist, who will apply the treatment protocol in the active control group (B A-S) and the participants. It is not feasible for both participants and therapists to be blinded, due to the nature of each intervention. All evaluations of the effectiveness of the treatment interventions will be carried out by two independent assessors who, although belonging to the research team of the study, do not know the type of intervention that each patient will receive, as well as the allocation of patients to the different treatment intervention groups (Kang, 2013, Opara *et al.*,

2013). The first assessor will administer the consent form, the demographic characteristics form, the questionnaires and recorded the primary outcome measures, as well as the secondary outcome measure prior to the start of the study. The second assessor will administer the compliance and complaint form to the participants and will record the primary outcome measure and the secondary outcome measures after the completion of the interventions. Data analysis will be performed by an independent biostatistician, an associate of the Musculoskeletal Physiotherapy Research Laboratory of the University of West Attica (UNIWA), who will not know the group in which each participant will have been allocated.

2.5.1.3. CONDUCT OF RESEARCH - STATEMENT OF CONSENT

The technique of ATM of the Feldenkrais method will be applied at the “Mikis Theodorakis” Multipurpose Center for Cultural, Sports and Social Activities of Ilion in Athens, Greece, in collaboration with the Musculoskeletal Physiotherapy Research Laboratory of the University of West Attica (UNIWA). The acupuncture treatments, the teaching of stretching (which will then be carried out at home) 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, in collaboration with the Musculoskeletal Physiotherapy Research Laboratory of the University of West Attica (UNIWA). 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 patients agree to participate in the research and 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 will assess all the patients who will come to the outpatient clinics and will be diagnosed by them with chronic non-specific neck pain or will have already a diagnosis of chronic non-specific neck pain by their treating physician. The

assessment of the patients will be carried out according to the inclusion and the exclusion criteria that will be defined in this 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 inclusion criteria

1. **Diagnosis of chronic non-specific neck pain.**
2. **Duration of the symptoms at least three months before the initial assessment and their participation in the study.**
3. **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, the cases that do not meet the above inclusion criteria or meet at least one of the exclusion criteria listed in the following table (Table 2), will be excluded. The remaining patients 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 - Filho *et al.*, 2017).
2. History of neck fracture or injury (Campa - Moran *et al.*, 2015; Dibai - Filho *et al.*, 2017) in the last year.
3. Head, face or neck surgery (Dibai - Filho *et al.*, 2017)
4. Active cervical hernia with radicular symptoms or severe degenerative diseases in the cervical spine (Dibai - Filho *et al.*, 2017)
5. Systemic diseases (diagnosed rheumatic, metabolic and immunological diseases) (Edwards & Knowles, 2003; Wilke *et al.*, 2014; Campa - Moran *et al.*, 2015; Cerezo - Téllez *et al.*, 2016; Dibai - Filho *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 (Edwards & 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 (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 who will agree to undergo the interventions, will fill out the demographic characteristics form and the questionnaires.

2.5.1.7. PERSONAL DATA AND DEMOGRAPHIC CHARACTERISTICS

The personal data that will be collected from each participant will be kept anonymous. Personal information, that can be used to identify the participant, at no stage of data collection will be requested, 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, associate of the Musculoskeletal Physiotherapy Laboratory of UNIWA. In addition, the technique of file encryption will be followed using VeraCrypt Containers (Bursać *et al.*, 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. Moreover, the computer 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 main researcher. 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, duration of symptoms, medication, and the presence of other medical condition, except for chronic non-specific neck pain. Regarding medication as well as the presence of another medical condition, they refer to drugs and diseases that are not included in the exclusion criteria.

2.5.2. INTERVENTION GROUPS

2.5.2.1. GROUP A ATM (FM)

ATM 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 the level of difficulty from relatively complex, applied to people with physical impairments to hypercomplex addressed to those with high motor requirements. The duration of each lesson varies between 30-60 minutes. In the beginning, simple, comfortable, gentle movements are performed that will gradually develop into complex ones, with a self-determined manner and rhythm by the trainee. The purpose is the teaching of execution rather than the completion of the movement. The improvement of awareness and the organization of the body is caused through the verbal instructions-orders or questions-problems that is posed by the educators of the method. The above aims at implementing a sequence of movements and focusing on different parts of the body (internal feedback). A corollary to this is the empathy of basic functions. Each lesson that will

be included in the protocol of the ATM group, 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 at improving the 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, the expansion of movement options, the learning of new movements and the presentation of a new way of composing them are attempted. 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 from 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 the A ATM group (intervention group) the ATM technique will be applied in group sessions (6-8 patients) by a physiotherapist, specialized in the FM with at least five years of experience. The ATM protocol will be implemented in ten sessions, two per week, of 50 minutes each, for a period of 5 weeks.

On the remaining days, home exercises will be given to the patients in the form of printed illustrated instructions for their correct execution. These ATM exercises, will be a repetition of the ATM lesson that they will have been taught and, will be performed once a day, until the next session, where participants will learn

and implement the next ATM lesson. The execution rate of the movements and the movement pattern will be individualized, as they dependent on each patient.

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 repertoire. 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 rotation 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 to the connection of the ankle joints with the hip joints and through them with the spine and head. Finally, the "On the side, the sternum becoming flexible" will mobilize the sternum in order to improve the rotation 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.

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 (Feldenkrais 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)

6.5.2.2. GROUP B A-S

In the B A-S group (active control group) before the implementation of the A-S protocol, a complete musculoskeletal assessment of the patients by an experienced physiotherapist trained in the identification of MTrPs, will be applied. The MTrP identification will be achieved by palpation of the muscles under examination (upper trapezius, levator scapulae, splenius capitis and cervicis), according to the criteria of Travell and Simons (1992). The points identified will be marked with indelible ink and recorded on a pain diagram. The patients' skin will be cleaned with alcohol before the acupuncture.

The A-S protocol will be performed in ten individual sessions, two per week, of 40 minutes each, for a period of 5 weeks. Acupuncture will be performed for 25 minutes by an experienced and licensed physiotherapist. It will include the insertion of a sterile disposable needle of 0.25 mm diameter and 25 mm length (DongBang Acupuncture, Inc., Korea) into standardized as possible appropriate local, regional and general points, that will modify the behavior of the pain in the area of the Cervical Spine.

Local acupoints will include:

- Small Intestine 14 (SI 14) which is located 3 Cun (1 Cun = maximum width of the patient's thumb) lateral to the lower border of the spinous process of the first thoracic vertebra (T1) (Sun *et al*., 2019) and is a common MTrP in the levator scapulae muscle.
- Gallbladder 21 (GB 21) which is located at the midpoint of the line connecting the acromion with the spinous process of the seventh cervical vertebra (A7) (Wilke *et al*., 2014; Sun *et al*., 2019) and is a common MTrP in the upper trapezius muscle.
- Gallbladder 20 (GB 20) which is below the occipital, in the depression between the insertions of the sternocleidomastoid and the trapezius muscles (Wilke *et al*., 2014; Sun *et al*., 2019).
- Bladder 43 (BL 43) which is located at the same height with the upper limit of the spinous process of the fourth thoracic vertebra (T4), 3 Cun lateral to the midline (Wilke *et al*., 2014).

Regional acupoints will include:

- Huato Jiaji C5 which is located paraspinal at the level of the fifth cervical vertebra (A5).
- Bladder 10 (BL 10) which is located on the horizontal line, passing between the spinous processes of the first (A1) and the second (A2) cervical vertebra and the oblique line, passing through the outer limit of the upper trapezius muscle, 1.3 Cun bilaterally of the vertical axis of the body, passing through the spinous processes of A1-A2 (Wilke *et al*., 2014; Sun *et al*., 2019).
- Governing Vessel 14 (GV 14) in the depression, inferior to the spinous process of the seventh cervical vertebra (A7) (Karavis, 2011; Wilke *et al*., 2014).

General acupoints will include:

- Triple Energizer 5 (TE 5) which is located 3 cm above the joint line of the wrist, at the dorsal surface of the forearm between the radius and ulna (Wilke *et al*.,2014; Calamita *et al*., 2018)
- Large Intestine 4 (LI 4) in the hollow of the radial side of the hand, approximately at the midpoint of the 2nd metacarpal.

After the needle will be removed, firm compression will be applied to the injection sites for 40 seconds to prevent any microbleeding (Campa - Moran *et al.*, 2015). The protocol acupoints are listed in Table 4.

Table 4. Biomedical acupuncture protocol points

Local	Regional	General
SI 14 (MTrP in the levator scapula muscle) GB 21 (MTrP in the upper trapezius muscle) GB 20 BL 43	Huato Jiaji C5 BL 10 GV 14	TE 5 LI 4

Potential events, except for 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 cream or ointment containing calcineurin inhibitors or a corticosteroid cream, gel or ointment. 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 stretching 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, once a day, after prior instruction by the same physical therapist. Stretching will be applied to the following muscles: upper trapezius, levator scapulae, scalene, cervical extensors (splenius, spinalis, semispinalis, longissimus capitis and cervicis, iliocostalis cervicis, multifidi and suboccipital), and sternocleidomastoid. According to Häkinnen et al*.,* the duration of each stretch will be 30 seconds and will be repeated three times (Häkkinen *et al.*, 2007), with one minute rest in between sets and ten seconds rest between each try.

2.5.3. OUTCOME MEASURES

Primary outcome measures will be the sensitivity of pain and secondary outcome measures will be the ROM of flexion, flexion-extension and lateral flexion of the cervical spine, the endurance of the deep flexor muscles of the cervical spine, the respiratory function, the intensity as well as the sensory and affective dimensions of the pain, the functional capacity of the neck, the anxiety and depression, the fear of movement, the perception of fear and the attempt to avoid pain in relation to physical and work activities, the degree of destructive views about pain, the quality

of life and patients' perceived change in their health conditions. Furthermore, the compliance rate will be recorded.

The measuring tools were selected based on their validity, reliability, ease of application and clinical economy. The outcome measures were assessed before the start as well as at the completion of the therapeutic interventions at five weeks, for both groups.

2.5.3.1. PRIMARY OUTCOME MEASURE

2.5.3.1.1. PAIN SENSITIVITY (PRESSURE ALGOMETER)

The primary outcome measure will be the pain sensitivity and a pressure algometer (Commander® Algometer, JTECH Medical, Midvale, Utah) will be used, measuring the Mechanical Pain Threshold (MPT). This model is a handheld algometer with two 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. The head which will be used has an area of one square centimeter (1cm^2) and the unit of measurement for the MPT value is kilogram per square centimeter (kg/cm^2).

In this PhD thesis, the recording of the pain sensitivity will be performed at specific points such as the upper part of the trapezius muscle and the suboccipital region, as the pressure algometer has shown high intra-rater reliability when applied to the upper trapezius muscle (Intraclass Correlation Coefficient / ICC: 0.85-0.86) and the suboccipital region (ICC: 0.84-0.93) in patients with chronic non-specific neck pain (Pérez-Martínez *et al*., 2020). The measurement in the suboccipital 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 cm 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 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 will be discarded since it will be considered as a trial. The average of the two consecutive measurements (second and third) will be calculated and recorded as the final value (Wilke *et al*., 2014; Pelfort *et al*., 2015). The force that will be applied for the measurements will be perpendicular to the body surface and the rate of pressure increase constant at 1 kg/cm^2 per second (Reeves *et al*., 1986; Koo *et al*., 2013), because if it is not constant the possibility of incorrect measurement will be increased.

2.5.3.2. SECONDARY OUTCOME MEASURES

2.5.3.2.1. CERVICAL RANGE OF MOTION (INERTIAL SENSOR)

Secondary measurements include range of motion (ROM) of flexion, flexion-extension and lateral flexion of the cervical spine. It will be recorded using the Moover® 3D Inertial Motion Sensor (Sensor medica; Guidonia Montecelio, Roma, Italia). This device has dimensions 36×32×12mm and weight 15gr (including the battery), allows goniometric evaluation, acceleration and rotation and converts them into electrical signal. The accelerometer can record ROM and acceleration values in three axes (Thomas *et al*., 2018). Through the software application, all recorded data are converted into diagrams and an automatic report is displayed. 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.

The Sensor will be positioned in the center of the forehead on the frontal bone at the level of the glabella, which is above the nasal bridge, and it will be fastened around the head with the assistance of a strap (Thomas et al., 2018). Then the rater will calibrate the device in a standardized neutral body position or starting position.

The patients will be trained through standardized instructions using video-recorded movements and commands, to perform cervical movements (left-right rotation, left-right lateral flexion and flexion-extension) correctly. Patients will perform three full-ROM movements, in each plane of motion, pausing for one second at the end of the ROM. To avoid measurement errors due to trunk compensating movements, active stabilization of the trunk and the shoulders will be applied manually by the rater's hands placed over the distal clavicle and acromion region (Fletcher and Bandy, 2008) while sitting directly behind the subject and passive stabilization will be provided by the backrest of the chair. The validity and the reliability of the wearable motion sensors in cervical spine have been recorded in the literature (Anoro-Hervera *et al*., 2019; Elizagaray-García *et al*., 2021).

2.5.3.2.2. ENDURANCE OF THE DEEP CERVICAL FLEXORS MUSCLES (PRESSURE BIOFEEDBACK UNIT)

The endurance of the deep flexor muscles of the spine will be assessed with a pressure biofeedback unit (Chattanooga Stabilizer Pressure Biofeedback). It 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).

The craniocervical flexion test will be selected as it only evaluates the deep neck flexors and not the superficial flexor muscles (Strimpakos *et al*., 2011). This test has intra- rater (ICC: 0.63) and inter- rater (ICC: 0.86) reliability in NSCNP patients. Moreover, there is significant correlation between craniocervical flexion test

and NDI (a = −0.40), SF36- Physical Component Summary/PCS (a = 0.56) and NRS (a = −0.37) (Jørgensen *et al*., 2014).

2.5.3.2.3. RESPIRATORY FUNCTION (SPIROMETER)

For the evaluation of the respiratory function, a portable spirometer of the MIR company (MIR Spirodoc), with dimensions of the central unit and the removable head-turbine 101x48x16mm and weight 99g and 46x47x24mm and weight 17g respectively, will be used. This measurement tool 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).

Portable spirometers are reliable compared to spirometry in a pulmonary function laboratory, which is considered as the gold standard. Additionally, has been found correlation between measurements performed in the pulmonary function laboratory and measurements done by the patient at home on the same day, regarding the FVC (ICC: 0.94) and FEV_1 (ICC: 0.99) (Finkelstein *et al*., 1993).

2.5.3.2.4. INTENSITY AND QUALITY OF PAIN (SHORT-FORM McGILL PAIN QUESTIONNAIRE / SFMPQ)

Pain will also be assessed subjectively with the SFMPQ questionnaire which includes its intensity as well as its sensory and affective dimensions (Melzack 1987). It consists of 11 sensory and 4 affective descriptors of pain. The patient rates each description on a four-point Likert type intensity scale, where 0 – no pain, 1 – mild pain, 2 – moderate pain and 3 – severe pain. SFMPQ also includes a ten-point Visual Analogue Scale (VAS) and a six-point rating scale describing the present intensity of pain (PPI), where: 0=No pain, 1=Mild, 2 =Annoying, 3=Painful, 4=Horrible, 5=Unbearable. The total score amounts to 45 points -33 for the sensory subscale, 12 for the affective subscale, 10 for the VAS and 5 for the PPI- (Neurotoolkit 2020). Furthermore, the SFMPQ is comprehensible and can be completed by people of different educational levels (even primary school graduates). 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 *et al*., 2000).

The short form of the questionnaire was translated and validated to the Greek population in 2000 by Georgoudis et al. (2000) (the GREEK-SMFPQ/the GR-SFMPQ). The internal reliability of the Greek version of the SFMPQ has been indicated (Cronbach's α value = 0.71) (Georgoudis et al., 2000).

2.5.3.2.5 NECK DISABILITY (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 should choose only one, the one that best represents their 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 in 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. Very good test-retest reliability (ICC: 0.93) and high internal consistency (Cronbach alpha=0.85) was indicated. Relation between the change score in the NDI and Global Rating of Change (GROC) was found (Spearman correlation coefficient = 0.3, P = 0.02). The Standard Error of Measurement (SEM) and the Minimal Detectable Change (MDC) were calculated as 0.64 and 1.78 respectively (Trouli *et al*., 2008).

2.5.3.2.6. ANXIETY AND DEPRESSION (HOSPITAL ANXIETY AND DEPRESSION SCALE / HADS)

Anxiety and depression will be recorded by the HADS scale. It is a selfreport 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 (Hospital Anxiety and Depression Scale 2020).

The Greek version of the HADS has been proven to has good test-retest reliability ($ICC_{,HADS}$ = 0.944, $ICC_{,HADS\_depression}$ = 0.84 και $ICC_{,HADS\_anxiety}$ = 0.90) and high concurrent validity between the HADS, the Beck Depression Inventory (BDI) and the State-Trait Anxiety Inventory (STAI) ($BDI_{,HADS}$ = 0.75, $BDI_{,HADS\_depression}$ = 0.72, $STAI_{,HADS}$ = 0.76, $STAI_{,HADS\_anxiety}$ = 0.774) (Michopoulos *et al*., 2008).

2.5.3.2.7. KINESIOPHOBIA (TAMPA SCALE KINESIOPHOBIA / TSK)

Fear of movement 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 et al. (2005b) 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 score is 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 *et al*., 2005b).

2.5.3.2.8. FEAR AND AVOIDANCE OF PAIN (FEAR- AVOIDANCE BELIEFS QUESTIONNAIRE / FABQ)

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 et al (2005a). 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) (Georgoudis *et al*., 2005a).

2.5.3.2.9. PAIN CATASTOPHIZING (PAIN CATASTOPHIZING SCALE / PCS)

Pain catastrophizing will be calculated with the Pain Catastrophizing Scale (PCS). It 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 et al. (2006). The total form of Greek PCS has satisfactory internal consistency {(Cronbach's alpha = 0.91) and its subscales (R: a = 0.79, M: a = 0.75, H: a = 0.88)}. Total PCS has also satisfactory test-retest reliability {(ICC = 0.82) and the subscales (ICC: R: 0.87, M: 0.73, H: 0.86)}. Its convergent and divergent validity have also been demonstrated as PCS has high correlation with the CSQ (r = 0.89) and moderate correlation with the affective subscale of the SFMPQ (r = 0.38, p < 0.01), the sensory subscale of the SFMPQ (r = 0.23, p < 0.01), the kinesiophobia (a = 0.51, p < 0.01), the anxiety subscale of the HADS (r = 0.49, p < 0.01) and the depression subscale of the HADS (r = 0.45, p < 0.01) (Chatzidimitriou *et al*., 2006).

2.5.3.2.10. QUALITY OF LIFE (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; Physical Component Summary (PCS) -correlated with PF, RP, BP and GH- and 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. The SF-12 Health Survey has demonstrated its construct, convergent, divergent and concurrent validity in Greek general population (Kontodimopoulos *et al*., 2007).

2.5.3.2.11. CHANGE OF HEALTH CONDITION (GLOBAL PERCEIVED EFFECT / GPE)

The Global Perceived Effect (GPE) scale will rate the perceived change of the subject's health condition. It asks the patient to rate how much their condition has worsened or improved relatively to another predetermined point in time (Evans *et al*., 2014). It is a numerical scale which consists of only one question with 5 possible answers. This scale is often used in musculoskeletal conditions, especially when they are chronic, such as chronic neck pain (Meisingset *et al*., 2018). Despite the ease of application of the GPE, it is a challenge for patients to accurately remember the state in which they were recently and not to confuse the current state with the corresponding past state (Kamper *et al*., 2010).

2.6. COMPLIANCE RATE

In addition to the aforementioned, in the survey will also be recorded the compliance rate of the participants in the two interventions. This process will be carried out through a paper form that each participant will receive and complete at the end of the ten sessions. On this paper form 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 patients will have performed them or not.

Participants' compliance with the exercise program at home will be assessed in two ways. The first way will include objective criteria such as whether they did the

exercises that they were given, the frequency with which they implemented them and the way in which they performed them (i.e. continuously or with breaks). The second way will involve the subjective view of each participant, who will self-assess the compliance that they will have demonstrated. The two assessing ways of compliance will be reduced to percentage scales (0%-100%), where higher scores will indicate higher compliance.

2.7. 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 worth mentioning.

2.8. 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 BA-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.

2.9. STATISTICAL ANALYSIS

Quantitative variables will be expressed as mean and standard deviation (SD). Qualitative variables will be expressed as absolute (N) and relative (%) frequencies. Pearson's χ^2 test and Fisher's exact test (where it is necessary) will be used to compare proportions, as well as McNemar test will be used to compare the percentages of kinesiophobia between measurements. Student's t-test or nonparametric criterion Mann-Whitney will be used for the comparison of the quantitative variables between the two groups. The change in the used scales and other indicators of the participants over time will be tested using linear mixed models from which dependence coefficients (β) and their Standard Errors (SE) will be obtained. The group, the measurement (endline vs baseline) and their interaction term (to be tested in which extent the change is different between measurements in the two groups), will be introduced as independent variables. In the cases, where the interaction term will be found significant, sex, age, BMI and the symptoms duration will be introduced in the model (the chosen confounding factors are the most significant), in order to be tested if the interaction remain significant. Moreover, in the case that measurements at some outcome measures will be found to differ significantly at the initial measurement between the two groups, a result not due to systematic error but found to be due to random sampling. In these cases, their initial values will be entered into the mixed linear models as an independent variable to

ensure that the findings from the models are not due to the initial differences between the groups. In cases that will be found significant differences between baseline measurements, between the two groups, the initial measurements will be introduced in linear mixed models as independent variable, in order to be ensured that the findings from these models are not due to initial differences between the groups. All reported p values will be two-tailed and statistical significance will be set at $p < 0.05$. Analyses will be conducted using the IBM SPSS Statistics 26.0.

2.10. RESULTS

Through the research, the effectiveness or the ineffectiveness of the FM will be highlighted and comparisons will be made between the effect of FM and A-S, regarding specific parameters (outcome measures), that will be evaluated at specific times (before and after the completion of the intervention - five weeks). Findings will be drawn for each hypothesis of both research questions with the aim of verifying or rejecting them. In detail, pain sensitivity, cervical ROM, endurance of the deep neck flexor muscles, respiratory function, intensity and quality of pain, functionality and psychological factors will be assessed and contrasted between the two interventions. After comparing the mean values of the groups in each assessment for each outcome measure, it will be established on the first level if the method under consideration has benefits in patients with chronic neck pain. On the second level, it will be established if it shows statistically significant results compared to the A-S intervention, if non-significant differences are detected between the two groups or if the active control group predominates. The findings will be presented for each outcome measure separately.

2.11. DISCUSSION

In the discussion the results will be recapitulated, analyzed and related to the existing literature. Each studied parameter of each research question will be assessed separately and the correlation based on the results obtained from the existing literature, which will be 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, in order to draw safer conclusions and then to generalize the results.

The sample will consist of a wide age and social spectrum, which provides more reliability to the study and increases the power of the FM, giving the possibility of its application without limitations. Furthermore, a wide variety of parameters will be evaluated in a large sample size, providing the possibility of deriving statistically significant results. The number of the participants is satisfactory and larger than that of the majority of studies analyzed in the literature review. Additionally, recording the compliance rate is an additional advantage and is not included in the most studies.

In the limitations is included the design of the study, which is a 'single-blind' method, eliminating systematic error for the observer. Another limitation is represented by the heterogeneity in the severity of the patients' symptoms, which could be specified in the inclusion criteria. Also, the plethora of exclusion criteria, that were set due to the acupuncture may constitutes an obstacle to the promotion of the results in the general population. Last but not least, short-term or long-term follow-up will not be conducted.

2.12. CONCLUSIONS-CLINICAL IMPLICATIONS

The effect of ATM on a common clinical condition - chronic neck pain - will be established based on a standardized procedure with a single blind randomized controlled trial. The acupuncture-stretching combination is used by many researchers and the present study will contribute to the highlight of the effectiveness of this protocol in the examined clinical condition. Finally, a comparison of the two interventions will be carried out in terms of the evaluation parameters (pain sensitivity, cervical ROM, endurance of the deep neck flexor muscles, respiratory function, intensity and quality of pain, functionality and psychological factors).

It should be taken into account that due to the lack of literature the investigation of the effects of FM is an unknown field, while the proper function of the cervical spine is of paramount importance. It attributed to the effects of the neck in spin’s function, as well as the function of the upper extremity. Consequently, the ATM technique is a valuable resource in prescribing exercises for patients.

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