University of West Attica
Health and Care Sciences
Department of Physiotherapy

Date: 22/04/2025

Informed Consent Form

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

STATEMENT OF CONSENT

CONSENT FORMS
to participate in a research program
(The forms consist of a total of 8 pages)

You are invited to participate in a research project. Below (see **"Information for Patients and/or Volunteers"**) you will be given explanations in plain language about what will be asked of you and/or what will happen to you if you agree to participate in the program. Any risks that may exist or inconvenience that you may suffer from your participation in the program will be described to you. You will be explained in detail what will be asked of you and who or who will have access to the information and/or other materials that you voluntarily provide for the program. You will be given the period of time during which program officials will have access to the information and/or materials you provide. It will be explained to you what we hope to learn from the program as a result of your participation. You will also be given an estimate of the potential benefit to the researchers and/or funders of this program. **You should not participate if you do not wish to or if you have any concerns regarding your participation in the program**. If you decide to participate, you must state whether you have participated in any other research program within the last 12 months. **You are free to withdraw your consent to participate in the research program at any time you wish**.

All pages of consent forms must bear your name and signature. In case of illiteracy, a literate witness must sign, while participants can use their thumb impression.

Surname:	……	Name:	……
Signature/ Fingerprint:	……	Date:	……

Short Title of the Research Program in which you are invited to participate
Effect of the Feldenkrais method on pain and functionality in patients with chronic neck pain
Responsible for the Research Program in which you are invited to participate
Georgios Georgoudis, Professor

Are you giving consent for yourself or another person?	
If you answered for someone else above, then you gave details and their name.	

Question	Yes or No
Did you fill out the consent forms yourself?	
In the last 12 months have you participated in any other research project?	
Have you read and understood the patient and/or volunteer information?	
Have you had a chance to ask questions and discuss the Research Program?	
Were any questions you had satisfactorily answered and explained?	
Do you understand that you can withdraw from the research program at any time?	
Do you understand that if you withdraw, it is not necessary to give any explanations for the decision you made?	
Do you agree to participate in the research project?	
Which responsible did you speak to?	

Surname:	…….	Name:	……
Signature/ Fingerprint:	……..……	Date:	…….

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INFORMATION FOR PATIENTS and/or VOLUNTEERS

Purpose of the research

The purpose of the present study is to investigate the effect of the Feldenkrais method on reducing pain and improving functionality in patients with chronic neck pain. The above will be implemented through the comparison of the Feldenkrais method with biomedical acupuncture combined with stretching.

Potential risks

With reference to the Feldenkrais method in the international literature, no possible risks have been reported. Those resulting from the correct application of biomedical acupuncture are rare and most often include bleeding, tenderness or suggillation at the point of needle insertion (Harvard Medical School 2017) and infections -most commonly due to staphylococcus etc.-. Secondarily and extremely rarely, internal organ or tissue injuries predominating in the pneumothorax (Xu et al. 2013) as well as dermatitis (Harvard Medical School 2017) may occur. After removing the needle, compression is applied to the insertion points for 40 seconds with the aim of avoiding any micro bleeding (Campa-Moran et al. 2015). Incidents other than dermatitis will be dealt with in accordance with the section Management of adverse events

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INFORMATION FOR PATIENTS and/or VOLUNTEERS, continued:

Potential risks

reactions that may arise from acupuncture and the dry needling technique' described by the World Confederation of Physical Therapy's guide to the safe practice of acupuncture and dry needling and the specialist subgroup dealing with acupuncture (International Acupuncture Association of Physical Therapists – IAAPT). In case 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 containing calcineurin inhibitors. The affected skin can undergo 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 side effects result from improper sterilization and use of 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.

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INFORMATION FOR PATIENTS and/or VOLUNTEERS, continued:

Who participates in the research?

Anyone between the ages of 19-70 who has been diagnosed with non-specific chronic neck pain, with a duration of symptoms of at least three months prior to the initial assessment and participation in the study, is allowed to participate in this research. The symptoms may refer to the shoulder or the upper limb without being of radicular etiology, while the full ability to understand and communicate in the Greek language is required.

How will I participate in the research?

If you agree to take part in the research, you will undergo either ten group sessions of the Awareness Through Movement (ATM) technique of the Feldenkrais method or ten sessions of acupuncture combined with stretching. The sessions will be conducted over a period of five weeks, i.e. two sessions/week of 50 minutes and 40 minutes for Feldenkrais and acupuncture-stretching intervention (25 minutes acupuncture+15 minutes stretching) respectively. The ATM technique will be performed by a physical therapist specialized in the method with at least five years of experience, who will verbally guide patients through a sequence of verbal

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INFORMATION FOR PATIENTS and/or VOLUNTEERS, continued:

orders to perform specific sequences of movements aimed at promoting functional connections between the head, spine and shoulders. Similarly, biomedical acupuncture will be performed by a certified physical therapist with many years of experience in the use of the needle. The stretches that will be applied after the acupuncture will also follow a pre-planned procedure of application and explanations and are systemized to the maximum extent possible. They will be performed at home after being taught beforehand by the physical therapist who will apply the acupuncture.

How will I participate in the research?

Feldenkrais group participants in addition to the scheduled sessions will also receive home exercises in the form of printed illustrated instructions for their correct execution. Pain sensation, range of motion (ROM) of flexion, extension, lateral flexion of the cervical spine, the strength of the deep flexor muscles of the cervical spine and the respiratory function. You will also be asked to complete a series of questionnaires that elicit information about chronic neck pain and the dysfunction it causes. Their completion time is approximately 35 minutes.

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INFORMATION FOR PATIENTS and/or VOLUNTEERS, continued:

How will I participate in the research?

Finally, the compliance rate of the participants in the two interventions will be recorded in the following way: in each session, each participant will be given a printed form to fill in, in which the exercises to be performed at home will be written, and next to them, an X or O must be marked depending on whether they have been carried out or not. Each form after completion will be returned to the independent assessor. In case you are not comfortable with any measurement, please do not hesitate to request that it be omitted. You will be asked throughout the interventions not to take anti-inflammatory, analgesic and/or corticosteroid medications, as much as possible, while if you need to take any medication you should inform your therapist. The ATM technique of the Feldenkrais method will be applied in a specially designed space at the Multipurpose Center for Cultural, Sports and Social Activities "Mikis Theodorakis" of the Municipality of Ilion, with which the UNIWA has a cooperation agreement. Acupuncture treatments as well as assessment measurements for both interventions will be carried out in the pain clinic of the A΄ Anesthesiology Clinic of the Aretaeio Hospital.

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Do I benefit from taking part in the research?

Understanding your problem in a very detailed way will lead to the best treatment and individualization of your treatment. We consider your contribution to the study important because from your answers it will be possible to develop useful, valid and reliable tools for measuring neck pain and the dysfunction it causes.

Does the researcher benefit from the program?

No individual benefit is foreseen for the researcher from the program.

Privacy

At no stage of data collection will any personal information that can be used to identify the participant be requested, so that their personal data is inviolably protected. The data will be kept under the responsibility of the person in charge of the research project, who will have access to the material and/or the information you provided (demographic characteristics and questionnaires-assessment scales) for a period of five years from the moment you submit the consent forms. If the research results are published or presented at conferences, no personally identifiable information will be included.

Surname:	……	Name:	……
Signature/ Fingerprint:	……	Date:	……