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for acquisition the educational and scientific degree "PhD"

**A CLINICAL APPROACH BASED ON
THE BIOPSYCHOSOCIAL MODEL IN THE TREATMENT OF
CHRONIC NECK PAIN**

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The dissertation contains 202 pages, of which 67 pages are an overview, methodology of the scientific study with results – 109 pages, discussion – 11 pages, publications in connection with the dissertation work – three, bibliographic reference of 175 titles, of which 29 on Cyrillic and 146 in Latin.

The dissertation is illustrated with 7 figures, 4 histograms, 45 diagrams and 47 tables. IN the abstract retains the original numbering from the dissertation work. The survey is held at UMBAL "St. Anna" Sofia, The Physiotherapy and Rehabilitation Clinic.

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LIST OF ABBREVIATIONS USED

EG Experimental groups
LV Low frequency currents
PIR Postisometric relaxation
p.p. Percentage points
CMT Medium frequency modulated currents
FRM Physical and Rehabilitation Medicine
FTP Physiotherapy program
CNS Central Nervous System
MRI Nuclear magnetic resonance
APTA American Physical Therapy Association
CAD_R_t Chin-Acromion distance right
CAD_L_t Distance Chin–Acromion left
EAD_R_t Right Ear-Acromion Distance
EAD_L_t Distance Ear–Acromion left
CSD_t Chin–Sternum Distance
IPD_t Distance Index–Sub
IASP The International Association for the Study of Pain
Form_t Tingling
HA_t Headache
NDI Neck Disability Index
OA Osteoarthritis
PHQ-9 Patient Health Questionnaire
Pn Pain
Vrt_t Vertigo

1. INTRODUCTION

Chronic pain is a significant health problem worldwide and is the main symptom that prompts a patient to seek medical attention.

Chronic pain affects about 20% of the European population, with a prevalence of 45-80% with advancing age [135]. Data from a large-scale study show that chronic low back pain, migraine and depression are among the top five leading causes of disability and are defined as diseases of global burden - "disease burden" [61]. In low- and middle-income countries, the prevalence of chronic pain is 33% of the elderly population, 56% of the elderly, and 35% of the working population [112]. A large-scale study in Canada found that its prevalence was higher among women, especially among those over 40 years of age. The most common location of chronic pain is the low back, and the most common cause is osteoarthritis [148]. Neck pain is the next most common musculoskeletal disorder at the spine level, with a prevalence of 27% (year 2019) for adults [96]. The problem of influencing chronic non-specific neck pain is increasingly relevant as it affects persons of working age and is of increasing frequency due to the trends of mass use of screen devices and static loading of neck structures from an early age.

In recent decades, the concepts of pain and the early nociceptive model, where a specific lesion in the body is experienced as pain by the brain, have undergone development, being expanded and enriched. The International Association for the Study of Pain (IASP) definition as "an unpleasant sensory and emotional experience associated with tissue damage..." emphasizes the presence of both components – both tissue damage and the role of emotions and mood in the perception of pain. Depression, anxiety and emotional factors are present as the most common participants in the experience of pain.

The overlap of anxiety, depression, and chronic pain in debilitating syndromes such as fibromyalgia, osteoarthritis, irritable bowel syndrome, and others has been demonstrated. Mental disorders not only lead to increased pain intensity, but also contribute to an increased risk of relapse.

As a result, many healthcare professionals are developing a new approach to treatment based on therapeutic strategies to address symptoms of anxiety and depression and other psychological components of the pain experience. This approach proves to be more effective in the treatment of chronic pain. The biopsychosocial model is such an approach and presents chronic pain as a unique phenomenon influenced by multiple heterogeneous factors. It integrates all biological, psychological, and sociocultural factors that interact to shape individual responses to pain and overall behaviour [158, 78].

The specialty of physical and rehabilitation medicine (PRM) is typical of the complex and interdisciplinary approach to the treatment of diseases, such as the biopsychosocial approach to the treatment of chronic pain.

2. SCIENTIFIC RESEARCH METHODOLOGY

2.1. GOAL, TASKS, HYPOTHESES

The purpose of the present study is to track and compare the therapeutic effect of a physical therapy program, combined with methods to influence the psycho-emotional state, versus a conventional physical therapy program in individuals with chronic neck pain.

To achieve our goal, we set the following **research tasks**:

1. Research and analysis of risk factors in patients with chronic non-specific pain in the cervical region of the spine;
2. Monitoring and analysing the clinical manifestations of the examined patients;
3. Monitoring and analysing the therapeutic effect of the application of a conventional physiotherapy program (FT) in patients with chronic non-specific pain in the cervical region, in the short term (after completion of the therapy) and in the long term (after 3 months);
4. Monitoring and analysing the therapeutic effect of the application of a FT program in combination with methods to influence the psycho-emotional state of patients with chronic non-specific pain in the cervical region, in the short term (after completion of therapy) and in the long term (after 3 months);
5. Comparing and analysing the therapeutic effect of the application of a conventional FT program and one in combination with methods to influence the psycho-emotional state in patients with chronic non-specific neck pain in the short term (after completion of therapy) and in the long term (after 3 months) ;
6. Discovery and analysis of the correlative relationships between influencing the psycho-emotional state of patients and influencing clinical symptoms in patients with chronic non-specific pain in the cervical region;
7. Conceptualization of a model to optimize the evaluation and physiotherapy treatment of patients with chronic neck pain by including elements to influence their psycho-emotional state.

We worked on the following **hypotheses**:

1. The presence of height is assumed percentage of risk factors in the followed patients with chronic non-specific neck pain;
2. A change in the psycho-emotional state of these patients is assumed, with the presence of varying degrees of anxiety and depression;
3. The developed complex physiotherapy program, including the application of preformed physical factors (heat procedure, SCT) and kinesitherapy has a good therapeutic effect in the short and long term on the examined persons;

4. The application of a complex physiotherapy program in combination with methods to influence the psycho-emotional state in patients with chronic neck pain has a better therapeutic effect in the long term for the examined persons, compared to the conventional FT program;

5. Correlative relationships are suggested between influencing the psycho-emotional state of patients and influencing clinical symptoms in patients with chronic neck pain;

6. After analysis and comparison of the results of the two applied therapies, it can be proposed to optimize the methods of assessment and treatment of patients with chronic non-specific pain in the cervical region;

2.2. MATERIAL AND METHODOLOGY

Object of the study

Patients with chronic nonspecific neck pain of three or more months' duration were randomized into two experimental groups (EG). For the purposes of the study, 70 persons aged from 22 to 89 years, who passed through the Clinic of Physical and Rehabilitation Medicine (KFRM) at UMBAL "St. Anna" - the city of Sofia for the period from 01.2020 to 01.2023. The persons studied were selected according to precisely defined criteria, meeting the needs of the present development.

Criteria for inclusion in the study:

➤ Patients with chronic non-specific pain in the cervical region, (recurrent or persistent for more than 3 months) and imaging studies with data of varying degrees of cervical osteochondrosis and spondylosis;

➤ After obtaining oral or written informed consent for their participation in the study, in accordance with good clinical practice

Exclusion criteria from the study:

➤ Patients under 18 years of age;

➤ Patients over 85 years of age;

➤ Pregnant women;

➤ Patients with chronic pain of malignant origin;

➤ Condition after fractures or surgical interventions in the cervical region.

Organization and design of the study

The study involved 70 patients with chronic cervical pain (recurrent or persistent for more than 3 months) and imaging studies with evidence of varying degrees of cervical osteochondrosis and spondylosis.

The medico-sociological information about the patient was collected by conducting an interview, and the questions and the discussion of the complaints were based on a previously prepared methodology. A set of questions was selected and an outpatient chart was prepared for the purposes of the study. A personal file is prepared for each patient, which contains a completed outpatient chart (with demographic

indicators, description of pain, somatic comorbidity, risk factors), results of the performed clinical tests and copies of the available medical documentation related to the patient's current complaints.

During the history taking and clinical examination, symptoms related to cervical pathology such as pain at rest (using a numerical scale from 0 to 10), vertigo, headache, impaired sensation, radiation of pain were purposefully sought and evaluated. These indicators, as well as the assessment of difficulties in performing daily activities (through the Neck Disability Index - NDI) and the assessment of the patients' psycho-emotional state (through the "Patient Health Questionnaire" - PHQ- 9) were examined at the initial examination, after completion of the physiotherapy course and three months after the therapy.

Quantitative changes in spine mobility were also monitored by measuring the active range of motion, reported in cm for lateroflexion, rotation, flexion and extension in the cervical region, and mobility in the thoracic and lumbar spine regions using the sub-index sample (in cm) and are plotted in the outpatient card.

The participants in the study with chronic neck pain were divided into two groups:

Experimental group 1 (EG1) – 35 patients. EG1 patients underwent a course of a total of 20 procedures, including reshaped physical factors and a specialized kinesitherapy (CT) program. The procedures were carried out by a team of two rehabilitators, daily for seven working days. The same equipment and method of application were used.

Experimental group 2 (EG2) – 35 patients. EG2 patients also underwent a weekly course of physiotherapy treatment with preformed factors and CT. Added to this treatment are methods to influence the psycho-emotional state. A discussion of the illness was conducted, accompanied by advice focusing on pain and stress coping skills. They received a program of analytical exercises and training to perform them at home. They were also provided with an information brochure, which contains detailed instructions contains detailed instructions for dealing with the changes at the physiological, psycho-emotional, social level that occur in the presence of chronic pain. To improve daily activities, the brochure also provides ergonomic advice related to work activities and rest, as well as recommendations for an anti-inflammatory diet.

Patient follow-up was performed in two stages for both groups of subjects. In the first stage, the condition of the patients was assessed before and immediately after the FT treatment. In the second stage, the condition of the patients was evaluated in the third month after the FT course.

Methods for objectifying the results

The data required for the purposes of the study were collected following the described sequence of the intended components of the study.

Sociological methods

Anamnestic data were recorded in an outpatient chart, which contained demographic data, type and location of chronic pain and risk factors, somatic comorbidity, and current treatment. To fill out the work card, both information shared by the examined persons and information contained in the medical documentation provided by them is used. Subjects are asked open-ended questions about pain experiences, lifestyle changes as a consequence of pain, description and duration of pain, which are

recorded in detail in free text. The nature of the treatment carried out so far is also specified. It is also monitored for the presence of risk factors - smoking, neck injuries and overweight.

To objectify the patient's state of health, the available medical documentation was also studied, such as outpatient records from visits to general practitioners and relevant specialists, epicrisis from hospitalizations, documents from performed imaging and paraclinical studies.

Clinical research methods

All patients underwent a neurological status focused to detect symptoms of root damage: excitatory or absent, motor (in case of anterior root damage), sensory (in case of posterior root damage) and mixed, Neri's sign. A functional assessment was performed. Initial measurements and tests were made according to a specially developed individual slip, in which the studied indicators are applied.

From the *subjective indicators* are tracked:

- **Pain** at rest using a numerical scale of 0 to 10 (NAS)

It is a 10-centimeter ruler along which the numbers from 0 to 10 are located. The patient must choose the number that most accurately describes the strength of the pain. The total number of points is 10. In this way, a numerical expression of the intensity of pain during the examination is given.

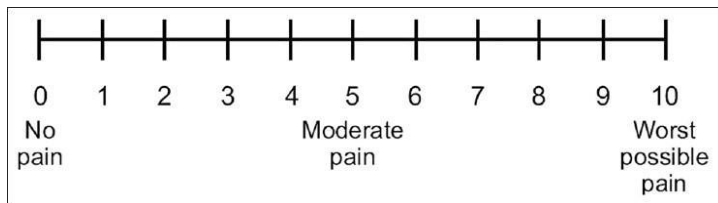


Fig. 4. Pain rating scale

(Measuring Pain in the Clinic – European Pain Federation)

- **Neck Disability Index** - NDI (Neck Disability Index - NDI) for coping with daily activities. The NDI is the most widely used and most strongly validated instrument for assessing disability in patients with neck pain due to degenerative changes in the intervertebral discs and in the structures of the cervical spine. It has been used effectively in both clinical and research settings in the treatment of this very common problem. The questions are divided into ten sections. Each section is scored from 0 to 5, with a maximum total score of 50 points. This is a self-assessment test of the degree of impairment of work ability, activities of daily living and social life as a result of the disease. After three months is a method of evaluating the extent to which FT treatment has produced a change in the patient's condition. (Application 1).

- **Dizziness.** It is examined using a scale for qualitative assessment in 4 grades: 1 – absent; 2 – weakly expressed; 3 – moderately expressed and 4 – strongly expressed.

- **The risk factors** were also monitored - past trauma in the cervical region, obesity, gender and age, smoking.

○ **"Patient Health Questionnaire" (PHQ-9)** to assess the presence of anxiety and depression. This is a quick self-assessment of mood and screening for the main signs and symptoms of depression. (Application 2). The scoring of each statement is as follows:

- Not at all: 0 points;
- Several days: 1 point;
- More than half of the days: 2 points;
- Almost all days: 3 points.

The total score for the nine questions is summed and can range from 0 to 27.

The result greater than 20t. indicates severe depression in which a combination of medication and psychotherapy (therapeutic counselling) would be indicated.

The evaluation between 15 and 19t. indicates significant depression (moderately severe) in which either antidepressant treatment or psychotherapy would be appropriate.

The evaluation between 10 and 14t. suggests moderate depression. Answers indicated for this rating range included antidepressants or psychotherapy. For some people in this range, counseling and advice alone may be appropriate.

The result between 5 and 9t. shows symptoms of mild depression that would require depression training, guidance on counselling when symptoms increase, and reassessment after one month.

The following are tracked from the *objective indicators*:

○ **Mobility in the cervical spine** in the frontal, sagittal and horizontal planes by measuring active range of motion. The mobility of the cervical spine is measured in cm after turning the head in the corresponding direction. The protuberantia mentalis of the lower jaw, the manubrium sterni of the sternum, and the acromion scapulae bilaterally are used as bone marks for measuring the respective distances. Normally these distances are the same.

In the sagittal plane - for flexion-extension - the mentosternal distance at maximum flexion and extension in the cervical part of the spine is taken into account in cm;

In the frontal plane - the lateroflexion to the left and right - the distance ear (uvula) - acromion in cm is measured at the maximum tilt of the head to the right and left;

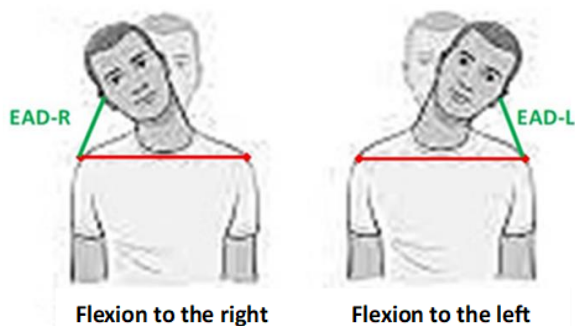


Fig. 5. Ear-acromion distance

In the rotator plane - for rotation - the mentoacromial distance is taken into account at maximum head rotation to the left and right.

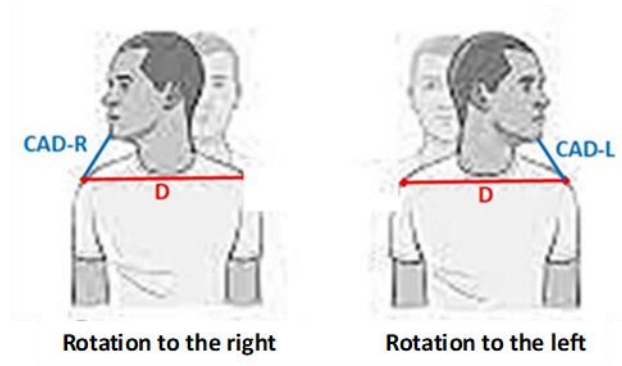


Fig. 6. Beard-acromion distance

- **Mobility of the spine** in the thoracic and lumbar parts is recorded with the maximum forward tilt sample (index - below) - from i.p. standing, resting on heels, the body leans (bends) forward. With normal mobility, the toes rest on the floor. If it is impossible to touch the floor, the distance between the index and the floor is counted in cm. With greater mobility, the examinee steps on a 10-30 centimetres pad and the distance, which is in plus cm after the pad, is counted.
- **Determining the body mass index** - it is calculated by dividing the value of the weight, measured in kilograms, by the height in meters raised squared.

$$\text{BMI} = T(\text{kg}) / P2(\text{m})$$

The aim is to detect excess weight as a risk factor for chronic neck pain.

Methods of statistical analysis

One of the main tools used to realize the purpose of the present study is the practical application of various statistical methods and corresponding statistical programs.

Statistical analysis was performed using IBM SPSS Statistics 19. IBM SPSS Statistics 19, Microsoft Office and Adobe Photoshop were used for graphical presentation of the results.

The statistical analysis methods used are based on the following samples:

A. The main **two independent samples** are the two experimental groups - **EG1** and **EG2**. The definition and methods of distribution of these two base samples (groups of followed-up patients) are described in detail in Chapter 4;

The moments of recording the values of the observed indicators are also described there. Almost all indicators were recorded at three points in time: "Immediately before therapy"; "Immediately after the end of therapy"; "Three months after therapy." Exceptions are several indicators registered once before the therapy: gender, age, body mass index, harmful habits.

Due to the fact that the registrations in both Experimental groups take place at the same times relative to the start of therapy, we obtain, within each group, three related samples depending on the time of registration. Moreover, due to the fact that in both Experimental groups the registrations are performed

synchronously with respect to the beginning of the therapy, we can study the respective samples in parallel. Thus, we implement a database of two groups of samples:

B. Two separate groups of three related samples - the values of the indicators at the three points of registration - "Before therapy", "Immediately after therapy", "Three months after the end of therapy" for both EG1 patients and patients of EG2. This provides three pairs of linked samples within each experimental group – they are called "linked" because they track changes in parameters over the course of therapy for the respective group;

C. Three groups of two independent samples each – track the changes in the values of the variables in parallel for the two experimental groups at each of the three time points. This interpretation provides an opportunity to statistically compare the treatments applied in the two groups both as a whole and in individual stages.

Based on the main purpose and tasks of the study, as well as the volume and type of data, the following statistical methods were used in conducting the study:

Descriptive analysis

Depending on the nature of the variables, standard methods of analysis were used. Additionally, positional averages are emphasized as appropriate for describing the condition of groups of patients. Various methods have been used for visualization, combining tabular and graphical presentation of information. Thus, it is guaranteed to be possible both to follow the changes of the indicators during the therapy (horizontal comparison within the experimental group), and to parallel and synchronously compare the results of the separate stages between the two groups.

Special emphasis is placed on the subjective non-dichotomous indicators: Pain (Pn), Cervical Disability (NDI), Mood Assessment Questionnaire (PHQ 9), again within groups and between patients from both groups EG1 and EG2.

Due to its importance for the outcome of the treatment, special attention is paid to monitoring the degree of depression through the indicator "Psycho-emotional state" for both groups.

The descriptive analysis concludes with an examination of the three dichotomous indicators: Headache (HA), Vertigo (VRT), Numbness of upper limbs (Form) during the three treatment periods, separately for each of the two experimental groups.

Nonparametric methods

One of the main non-parametric tests used when comparing two dependent (related) samples is the Wilcoxon Signed Ranks Test. The test compares means and is applicable to variables with at least an ordinal distribution.

The variables Pain (Pn), Cervical Disability Index (NDI), Psycho-Emotional Status Questionnaire (PHQ 9), Cervical Mobility (CAD_R, CAD_L, EAD_R, EAD_L, CSD, IPD) were examined by the Wilcoxon test. The test was used for the two Experimental groups to analyse the indicators in three pairs of moments:

- "Before therapy" \Leftrightarrow "Immediately after therapy";
- "Immediately after therapy" \Leftrightarrow "Three months after therapy";

- “Before therapy” \Leftrightarrow “Three months after therapy”.

McNemar Test (McNemar Test) is a non-parametric test, analogous to the Wilcoxon test, but for variables with a dichotomous distribution. The t test was used to compare the means of two independent samples for the two Experimental groups separately at the three time points of registration for variables with dichotomous distribution - Headache (HA), Vertigo (VRT), Numbness of upper limbs (Form).

Parametric methods

The most important condition for the application of parametric methods for statistical analysis is to meet the requirement for a normal or close to normal distribution of the investigated quantities.

The One-Sample Kolmogorov-Smirnov. Test was used to verify the condition. The test was applied to all variables (except those with dichotomous distribution), separately for each experimental group, and in each of the three moments of registration – a total of 6 samples.

Two Independent Samples t-test. The procedure is used to test two independent samples. Tests the significance of the difference between the two sample means. Three pairs of independent samples are analyzed - in each of the three moments of registration in the two experimental groups. The requirement of independence of samples is mandatory.

Paired Samples Test. This test is used to analyse two related samples. Three pairs of related samples are analyzed –

- “Before the therapy” \Leftrightarrow “Immediately after the therapy”;
- “Immediately after the therapy” \Leftrightarrow “Three months after the therapy”;
- “Before the therapy” \Leftrightarrow “Three months after the therapy”.

It is applied separately to each of the two experimental groups.

Correlation analysis is based on the calculation of correlated, stochastic dependence between random variables. The dependencies between the variables before and after the therapy, as well as immediately after the therapy – 3 months later, were investigated. The analysis was performed standardly using the procedures for Analysis of Variance (ANOVA) and Multivariate analysis of variance (MANOVA), in this case using dummy variables.

Special attention is paid to the subjective variables Pain (Pn), Cervical Disability Index (NDI), Psycho-Emotional Status Questionnaire (PHQ 9). The relationships between the three subjective variables at the three separate moments of registration were analysed separately for the two experimental groups. The results of the analysis are shown in 6.11.1.

Regression Analysis – While correlation analysis characterizes the strength of the relationship between two variables, regression analysis serves to determine the type of that relationship and makes it possible to predict the values of the dependent variable from the values of another independent variable.

Classical procedures for regression analysis were used - ANOVA and MANOVA; the results are illustrated graphically with the means of IBM SPSS 19, Microsoft Office and Adobe Photoshop.

Description of variables studied

Clinical symptoms presented as subjective and objective variables can be divided into three groups according to the type of their values – Ordinal, Nominal and Scale (according to the terminology in SPSS).

As **Ordinal** can be considered three quantities:

Pain (Pain) 0 – 10 pts.

Cervical Disability Index (NDI) 0 – 50 points.

Psycho-Emotional Condition (PHQ) 0 – 27 pts.

Nominal values are Headache, Vertigo and Formication. These quantities are also dichotomous - we only count the presence (1) / absence (0) of the indicator.

Scale, or Metered, are all the quantities with which we consider the mobility in the cervical region and which in this case represent distances (in cm)

Table 4. Names of indicators

Table 4a. Names of subjective and dichotomous indicators

Pn_t	Pain – 0 – 10 pts.
NDI_t	Cervical Disability Index (NDI) – 0 – 50 points.
PHQ_t	Psychoemotional state (PHQ-9) – 0 – 27 items.
HA_t	Headache – 0 – absent, 1 – present
Vrt_t	Vertigo – 0 – absent, 1 – present
Form_t	Formication – 0 – none, 1 – present

Table 4b. The names of the indicators of mobility in the cervical region

CAD_R_t	Chin-Acromion distance on the right, cm
CAD_L_t	Distance Chin–Acromion on the left, cm
EAD_R_t	Distance Ear–Acromion on the right, cm
EAD_L_t	Distance Ear–Acromion on the left, cm
CSD_t	Distance Chin–Sternum, cm
IPD_t	Distance Index–Sub, cm

XXX_0 (t=0) – value immediately before therapy
 XXX_1 (t=1) – value immediately after therapy
 XXX_3 (t=3) – value 3 months after therapy

3. RESULTS AND ANALYSIS

3.1. Base scores

Distribution of patients from EG1 and EG2 by age

A total of 70 patients aged 22 to 87 years were included in the study. They were distributed in equal proportions in two experimental groups of 35 people each randomly.

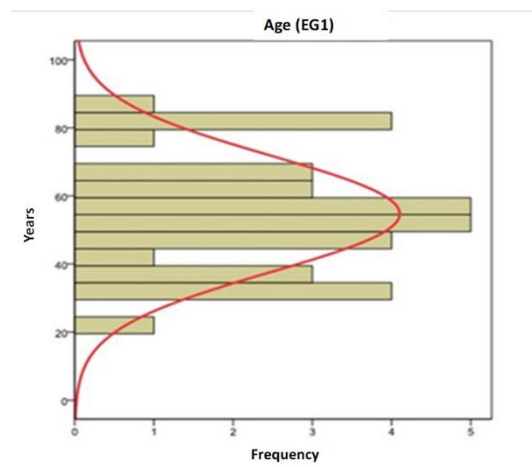
Table 1. Age of patients in EG1 and EG2

Age		Age - EG1	Age - EG2
N	Valid	35	35
Mean		54,7	58,9
Minimum		22	27
Maximum		87	83

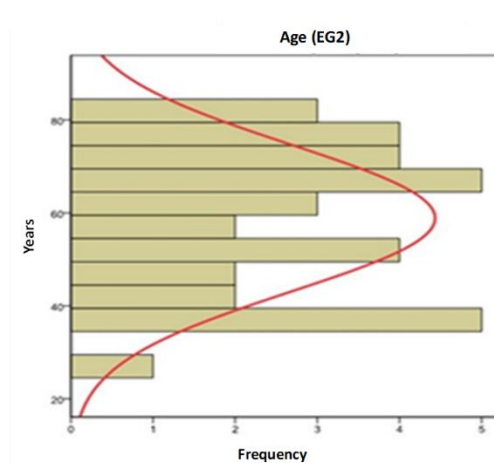
Table 1 shows the distribution of patients from the two groups by age. The mean age for EG1 was 54.7 years, with the youngest patient being 22 years and the oldest being 87 years. For EG2, the mean age was 58.8 years and patients ranged in age from 27 to 83 years.

When evaluating the age distribution in the two groups, no statistically significant difference was found - the standard error of the mean was 2.88 and 2.66, respectively.

Histograms 1 and 2 show the distribution of patients by age subgroups.



Histogram 1. Distribution of patients from EG1 by age



Histogram 2. Distribution of patients from EG2 by age

For a more natural representation of the increase in age (the higher age - above) an unconventional representation of the histograms (rotation by 90°) was used.

Distribution of patients from EG1 and EG2 by gender

Followed patients were 18 men (25.7%) and 52 women (74.3%), respectively. Diagram 1 shows this distribution for the two groups, with men being a similar percentage – 28.6% for EG1 and 22.9% for EG2. In both groups, women make up more than 2/3 of the observed patients. The higher percentage of women is consistent with literature data on a higher frequency of neck pain complaints in women compared to men.

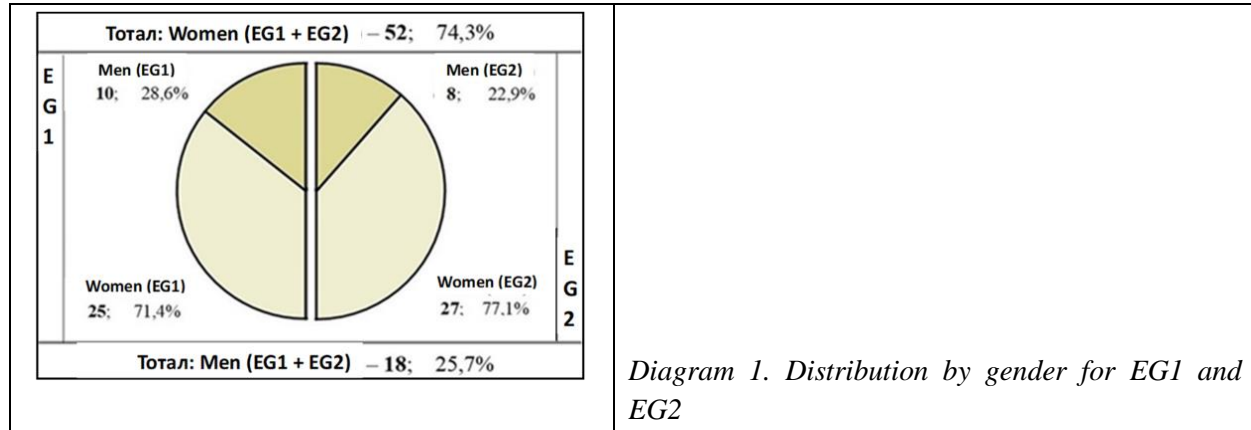


Diagram 1. Distribution by gender for EG1 and EG2

Analysis of risk factors

The presence of obesity, trauma and smoking, type of occupation were monitored as risk factors for a more difficult influence on pain in the cervical region and as a prerequisite for its chronicity.

In treated patients, based on height, weight and age, a Body Mass Index (BMI) was calculated as an indicator to determine the presence of obesity.

Table 3 presents a descriptive analysis of BMI for EG1 and EG2.

Table 3. Body mass index (BMI) of patients in EG1 and EG2

		BMI – EG1	BMI – EG2
N	Valid	35	35
	Missing	0	0
Mean		25,4	25,6
Standard error of the mean		0,77	0,65
Median		25,8	25,8
Standard deviation		4,53	3,83
Minimum		15,9	19,3
Maximum		41,4	35,4
Percentiles	25%	22,8	23,4

50%	25,8	25,8
75%	27,2	27,3

The average value of BMI for EG1 is 25.4 and for EG2 – 25.6. And the maximum value of the index for patients from EG1 is 41.4, and for those from EG2 – 35.4.

Half of the patients in both groups had a value up to 25.8, represented by the median. This shows the absence of obesity for at least 50% of the respondents.

A more accurate assessment of the presence or absence of obesity for patients in both groups can be obtained from Chart 2:

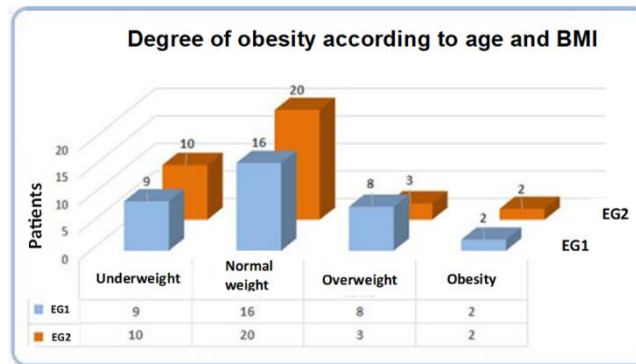


Diagram 2. Degree of obesity for EG1 and EG2

The diagram shows that 16 patients (45.7%) from EG1 and 20 (57.1%) from EG2 were of normal weight. Underweight has a similar percentage in both groups: 25.7% (9) of EG1 and 28.7 (10) of EG2. There were only 2 obese patients (5.7%) in both EG groups.

The presence of injuries in the cervical region was monitored as another risk factor - presented in Diagram 3. The frequency of old injuries in the cervical region among the treated patients was identical for both groups - 8 people (22.9%) from each group.

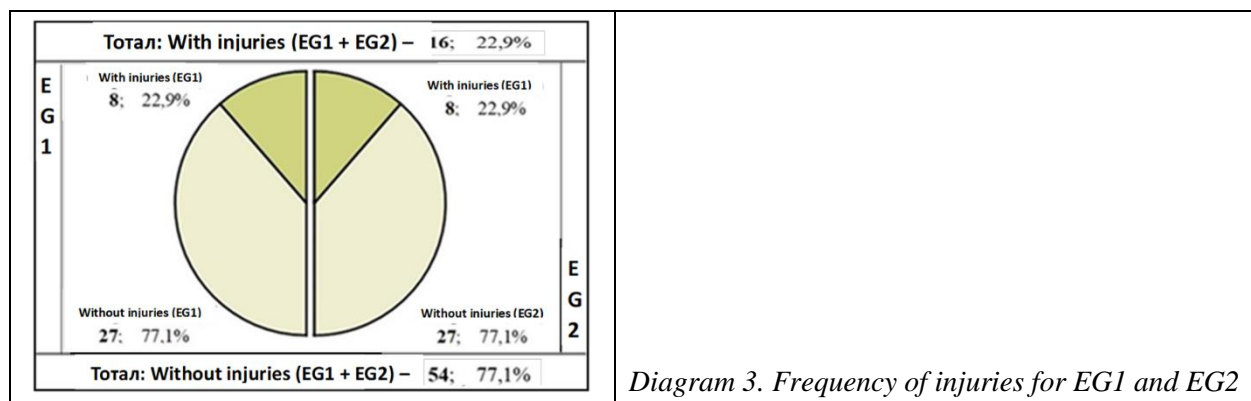


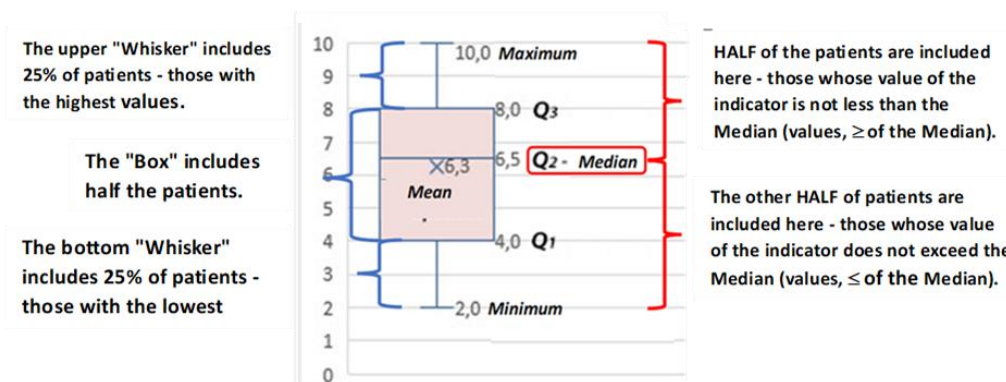
Diagram 3. Frequency of injuries for EG1 and EG2

Descriptive analysis of tracked indicators

Descriptive analysis involves a descriptive representation of the variables. This provides a convenient and efficient opportunity to compare variables over time within each Experimental Group. Moreover, thanks to the synchronization of the moments of registration of the values of the variables in the two EGs, it provides an opportunity to compare and analyse the progress of the treatment process in each group compared to the other.

To visualize the differences in results for EG1 and EG2, the studies are depicted using Box&Whisker plots. Their mean, minimum, maximum of each measure are presented, as well as the median and quartiles, as presented in the Box&Whisker plot legend.

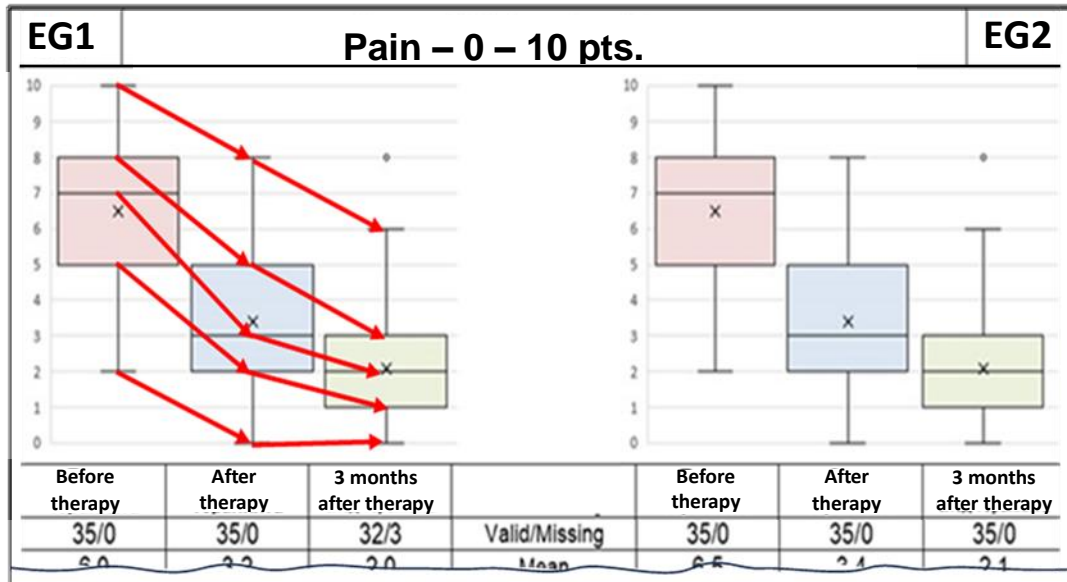
Box&Whisker διαγράμμι



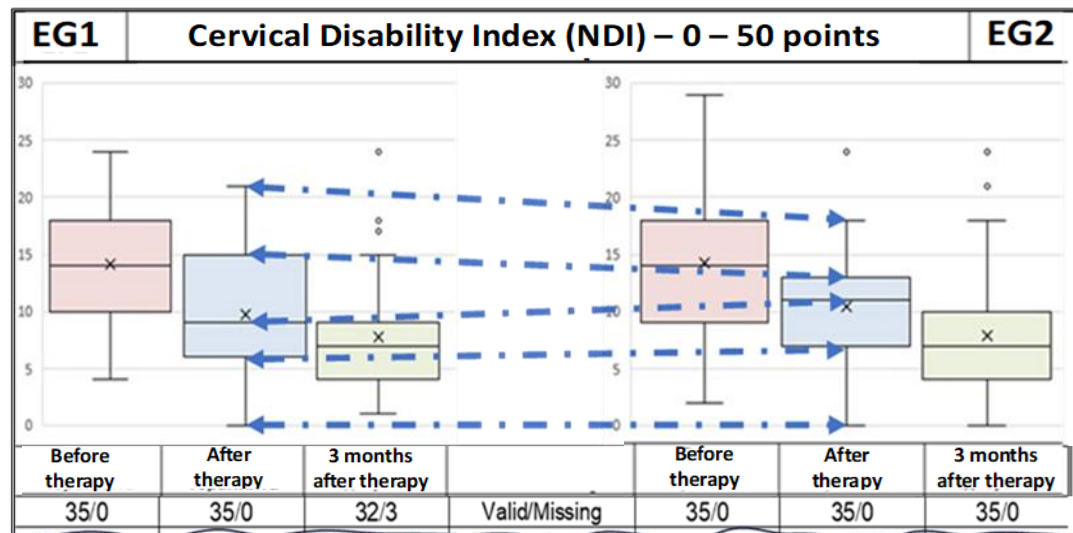
The median bisects the statistical series and often differs from the average of the various measures. It shows that half of the patients have an indicator value not exceeding the median value. The median is an average value, significantly more robust than the arithmetic mean, as it is not affected by possible extreme values of the indicator - the so-called outliers.

We present the descriptors for each of the three registration moments in parallel for each of the two groups. This provides a convenient and efficient way to compare changes over time within each EG, as well as to compare between the two groups at each time point, as well as the course of treatment in each group (compared to the other group).

The combination of three Box & Whiskers charts allows to track the trend in the change in the value of the indicator (the change in the patient's condition) during the treatment in each Experimental Group.



On the other hand, the combination of six Box & Whiskers diagrams - three for each Experimental Group makes it possible to track the values of the indicator (the change in the patient's condition) in parallel in both EGs for each stage of the treatment as well as to visualize the difference.



Descriptive analysis was performed for all subjective variables: Pain (Pn), Cervical Disability Index (NDI) and Psycho-Emotional Status Questionnaire (PHQ-9) and also for cervical mobility through the objective (measured) variables – Rotation through the chin-acromion distance to the right/left (CAD_R, CAD_L), Lateroflexion through the ear-acromion distance to the right/left (EAD_R, EAD_L). For Cervical Flexion-Extension by Chin-Sternum Distance (CSD), no statistically significant mean differences were found and no descriptive analyses were performed.

As an illustration, the combined diagrams for one subjective and one objective indicator are placed.

Tracking changes in the “Pain” indicator

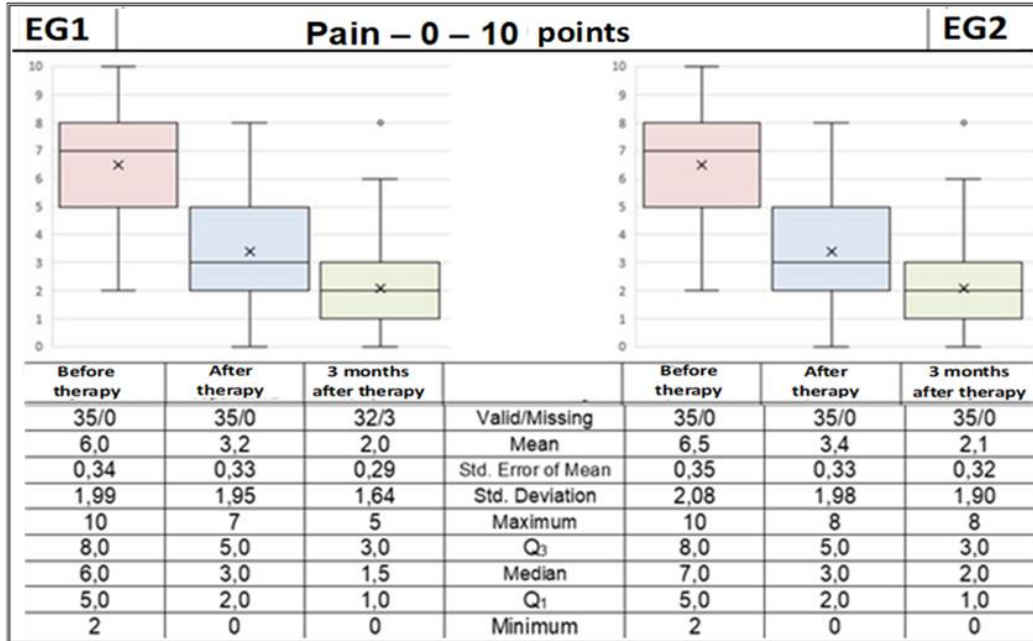


Diagram 5. Pain (0–10 points)

From the monitoring of the Pain indicator (Diagram 5), it is evident that the pain decreased significantly in both groups after the end of the physiotherapy course. Before the therapy, for half of the patients in EG1, the pain value was ≤ 6.0 points, and in EG2 – ≤ 7.0 points. But after the therapy, in both groups, half of the patients already had a pain value of ≤ 3.0 points. This represented a greater than 50% reduction in pain intensity for EG2 after completion of physical therapy. As the average value of this indicator for EG1 after the therapy is 3.2 points, and accordingly – 3.4 points for EG2.

At the follow-up of the third month after therapy, the average value of pain for both groups was identical – 2.0 points and 2.1 points for EG1 and EG2. This shows that the achieved effect in terms of pain is comparable for patients in both groups.

The analysis of the impaired functionality in the daily life of the patients using the NDI indicator is presented in Diagram 6. The improvement reported by the arithmetic mean value is comparable for both groups after the completion of the FT course - of 14.2 pts. starting average value for both groups, it drops to 9.8 pts. for EG1 and to 10.4 pts. for EG2. After 3 months, the median was 7.0 for both groups.

Regarding the psycho-emotional state, an improvement was reported at follow-up on the mean value of PHQ_9 (Chart 7). Although before the therapy the average value was higher for EG2 (8.8 points) compared to EG1 (6.8 points), the decrease in the values of this indicator after physiotherapy was comparable for both groups - by 2.1 points for EG1 and with 2.2 points for EG2.

Follow-up of changes in objective indicators also showed a good effect on cervical mobility for patients in both groups. As an example, the diagram for mobility in one of the planes is placed:

**Tracking changes for cervical rotation
(by measuring the chin-acromion distance) on the right.**

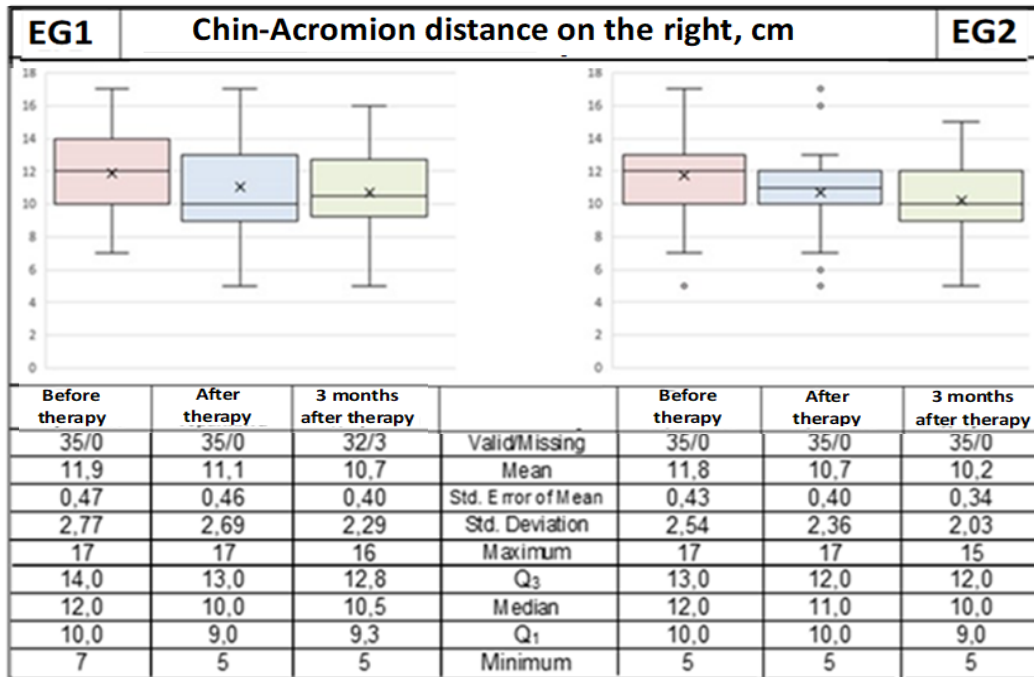


Diagram 8. Rotation - chin-acromion distance (cm)

Descriptive analysis of the Right Chin-Acromion Distance indicator (Diagram 8) shows that mobility in the cervical spine for rotations to the right shows a more significant improvement immediately after the end of physical therapy. A better mean change was achieved from 11.8 cm to 10.7 cm for EG2, and from 11.9 to 11.1 cm for EG1, respectively. After 3 months, the values showed a decreasing trend, and the mean values were 10.7 cm for EG1 and 10.2 cm for EG2. The effectiveness of the applied therapy for EG2 is higher compared to that for EG1 in affecting the rotation of the right in the cervical lobe after the completion of the FT course, and this advantage is preserved after 3 months.

Cervical spine's range of motion analysis for rotations to the left (Chart 9), show a more significant improvement again immediately after the end of physiotherapy. As the improvement in the average values of the two groups is almost identical – for EG1 from 11.6 cm before physiotherapy to 10.7 cm after; and for EG2 – from 11.5 cm to 10.7 cm. The achieved effect in both groups was maintained even after 3 months of the end of the therapy, again with slightly lower values for EG2 – 10.1 cm, compared to 10.6 cm for EG1.

After completion of the FT course, the improvement in left rotation in the cervical lobe was slightly predominated for EG2 patients.

In an identical way, the changes in the mobility of the cervical lobe of the spine and in the other planes were tracked.

Tracking the dichotomous variables

In a similar way - again by combining the graphs from the six samples into one diagram - the complex assessment of the clinical complaints and symptoms of the patients with chronic pain in the cervical region was built, tracking the presence of Headache (HA), Vertigo (VRT), Numbness of upper limbs (Form) (Diagrams 26-28). The percentage distribution of the tracked symptoms - reported by the patients of the two Experimental groups at different times of the treatment (Before the therapy / After the therapy) and the follow-up of its results (Three months after the therapy) is graphically presented. Here, too, the chosen way of presentation guarantees an analysis of the change in the condition of the patients in the various stages within the framework of one experimental group, as well as a comparison between the groups.

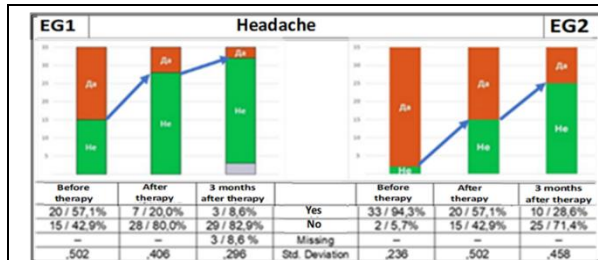


Diagram 26. Presence/absence of Headache

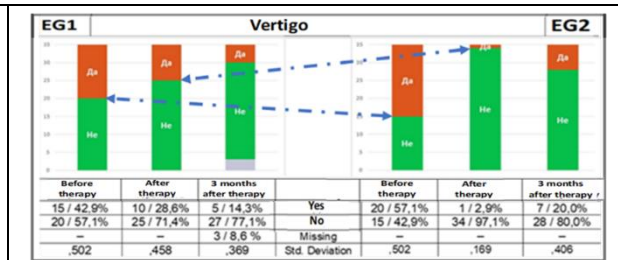


Diagram 27. Presence/absence of Vertigo

Track Changes in Formication (Form)

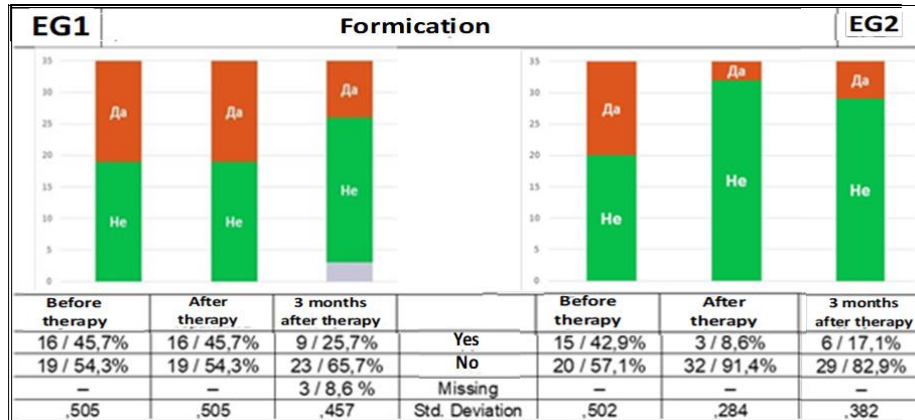


Diagram 28. Presence/absence of Numbness depending on the applied therapy (EG1 or EG2) and the moment of registration

From Diagram 28 it is clear that numbness was reported by 45.7% of EG1 patients before therapy, which remained unchanged after completion of FT. For EG2, out of 15 patients (42.9%) before the therapy, only three (8.6%) remained after the end of the physiotherapy, i.e. we have a significant decrease of 34.3 p.p. compared to no effect in EG1 patients. Three months after therapy, the frequency of this symptom decreased by 20 pp. – out of 16, 9 patients remained with numbness (EG1). After three months of therapy, numbness was present in 6 patients from EG2, with 3 less than EG1. Numbness was affected for EG2 patients both after completion of FT and three months after.

Regarding vertigo for EG1-, from 15 patients (42.9%) before therapy, decreased to 10 (28.6%) after completion of physical therapy. For EG2, out of 20 patients (57.1%) before therapy, only one (2.9%) remained after completion of physical therapy. There was a significantly better effect on vertigo for patients from EG2, immediately after completing the FT course, but after three months the frequency of vertigo was comparable for both groups (Diagram 27).

From EG1, headache was reported by 20 (57.1%) of the patients before therapy, which decreased to 7 (20%) after completion of FT – the reduction was by 37.1 pp. A significant number of patients from EG2 – 33 (94.3%) had headache before therapy. After the end of the therapy, they are already 20 (57.1%), which is a decrease of 37.2 pp. Three months after the therapy for patients from EG1 - out of 7, 3 remain with headaches, for patients from EG2 - out of 20, 10 remain with headaches. The effectiveness of the therapy in terms of headache was comparable for both groups, both after completion of the FT course and three months later (Diagr.26).

Graphical comparison of change in subjective indicators

An original method based on four charts (for each indicator), each of which is composed of two combined histograms, has been chosen to present the subjective indicators Pain, Disability Index in the cervical region and Psycho-emotional state:

- The combination of **two histograms** - one for the values of the indicator **before the therapy**, the second – for the values of the same indicator **after the therapy** allows to track and highlight the change as a result of the therapy. (Diagrams 12, 16 and 20 – for EG1 and 13, 17 and 21 – for EG2);
- The combination of **two histograms** - each one for the values of the indicator **before the therapy** - the left for EG1, the right for EG2 - allows to control the equality of the Experimental groups in relation to the set of patients (Diagrams 14, 18 and 22);
- The combination of **two histograms** - each one for the values of the indicator **after the therapy** - the left one for EG1, the right one for EG2 - allows to analyse the impact of the therapy in each Experimental Group (Diagrams 15, 19 and 23);

The histograms making up each pair are rotated from the traditional horizontal position to facilitate comparison and highlight change.

The method is illustrated with the Index of disability in the cervical region. The remaining two subjective indicators can be seen in the dissertation.

Comparing Cervical Disability Index (NDI) values

We compare the change in the indicator for patients from EG1 and EG2 before and after therapy, i.e. what effect the therapy had on the index (NDI) value.

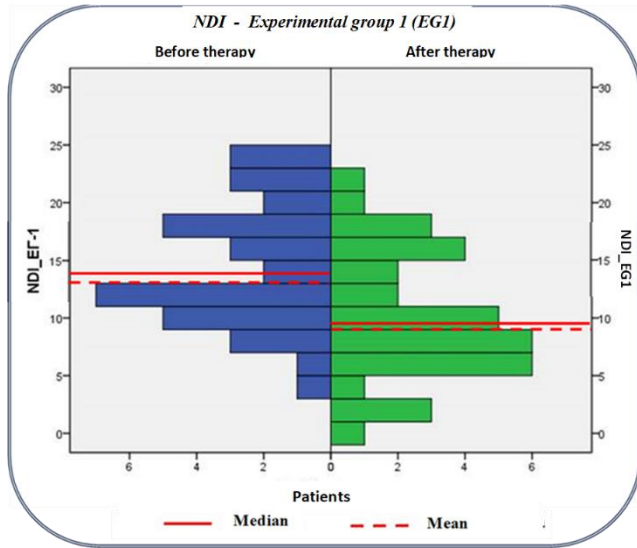
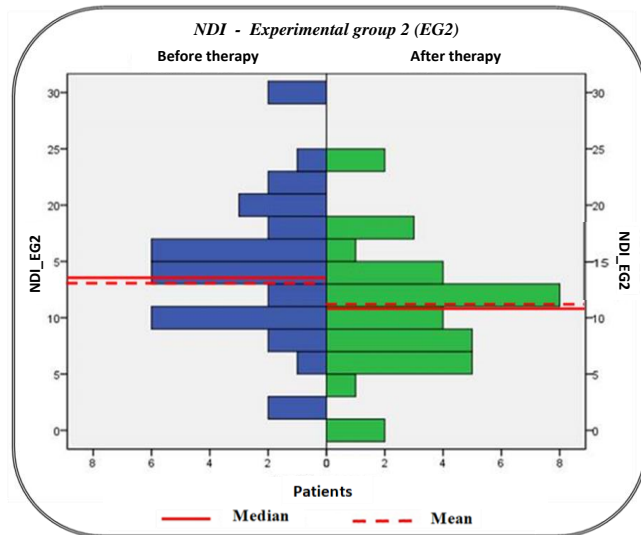


Chart 16. Cervical Disability Index (NDI) in patients in EG1 before and after therapy

Chart 16 shows a decrease in the mean value of the Cervical Disability Index (NDI) and the median after the applied therapy for the EG1 patients.

Chart 17. Cervical Disability Index (NDI) in patients in EG2 before and after therapy

Chart 17 shows a decrease in the mean value of the Cervical Disability Index (NDI) and the median after the applied therapy for the EG2 patients as well.



We compared the level of cervical disability index simultaneously for the two groups before and after the therapy and evaluated the effectiveness of the two types of therapy applied.

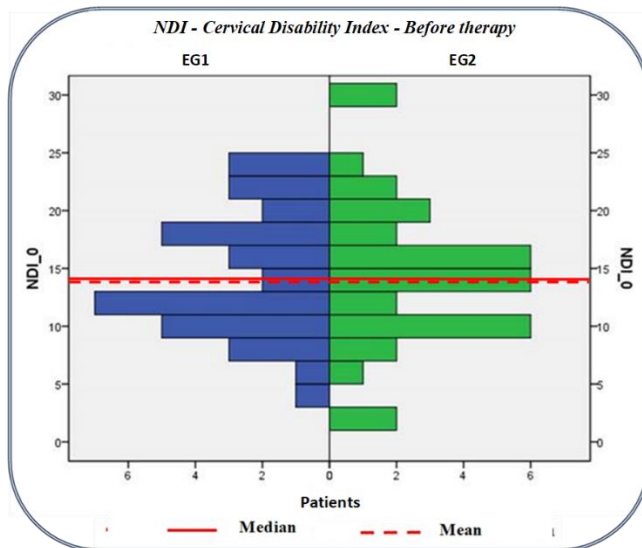
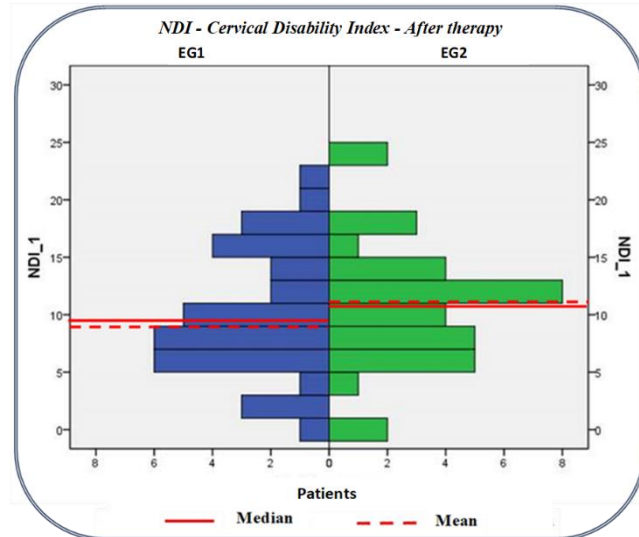


Chart 18. Cervical Disability Index (NDI) in patients in EG1 and EG2 before therapy

On Diagram 18, the values from EG1 are in the left half, and from EG2 in the right half. In this case, it can be seen that the patients from both groups have the same starting values of the index.

Chart 19. Cervical Disability Index (NDI) in patients in EG1 and EG2 after therapy

When comparing Charts 18 and 19, we find that the impact on the Cervical Disability Index (NDI) after completion of FT treatment is comparable for both groups, with a slight priority for EG1 patients.



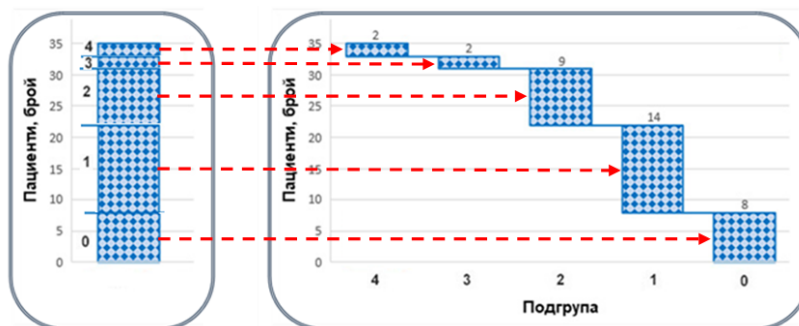
Similar charts and analyses were made for all subjective indicators.

Tracking the extent of depression through the indicator "Psycho-emotional state" (PHQ-9)

The PHQ-9 indicator has a total score for the nine questions from 0 to 27 items. Patients are divided into five subgroups depending on their results. The meaning of the different results is as follows:

- ✓ subgroup 4 - with a score greater than 19 points - indicates severe depression.
- ✓ subgroup 3 – with a score between 15 and 19 points indicates moderately severe depression.
- ✓ subgroup 2 – with a score between 10 and 14 points corresponds to moderate depression.
- ✓ subgroup 1 – a score between 5 and 9 indicates symptoms of mild depression.
- ✓ subgroup 0 - with a score of 0 to 5 items - without the presence of depression.

Diagrams 24 and 25 of the dissertation show the number of patients in the respective subgroups of EG1 and EG2, for each of the three moments of registration. Waterfall Charts are used as they are much more visual than Vertical Stacked Bar Charts.



Before the therapy, patients from EG1 mostly fall into subgroup 1 (with 15 patients) - with symptoms of mild depression, in subgroup 2 - with moderate depression, three of them, and four of moderately severe depression. A total of 22 patients had symptoms of depression to varying degrees. There were no patients with severe depression in the group. There were 13 patients without change in mood and psycho-emotional state - in subgroup 0.

After the EG1 therapy, there are no longer any patients with moderate depression, in subgroup 1 the patients have decreased from 15 to 9 and in subgroup 0 – they are now 21, with 8 more than before the therapy. We can claim that after the therapy, 8 patients no longer show any symptoms of depression.

The psycho-emotional state of a total of 14 patients changed after the therapy in the direction of improvement - reduction of symptoms of anxiety and depression for patients from EG1.

Three months after the therapy in EG1 – in subgroup 1, with mild depression, there are 8 patients, in subgroup 2, with moderate depression, only one patient remained, and there were no patients with severe depression. Most of the patients (23) are in subgroup 0, i.e. without symptoms of depression.

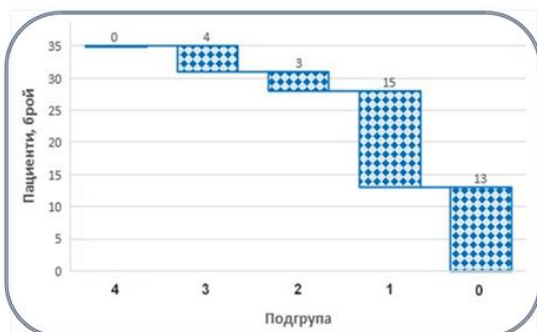
The graphs for patients from EG2 are similar. Before therapy, patients from EG2 mostly fell into subgroup 1 (14 patients), followed by subgroup 2 – 9 patients. There are also two patients each with moderately severe and severe depression. A total of 27 have a changed psycho-emotional state. Only 8 of them are without a change in mood.

After the therapy in EG2, there are no more patients with moderately severe depression, but two with severe depression remain. In subgroup 3 – patients decreased from 9 to 5, i.e. two with severe and 4 with moderate depression now have milder signs of depression. In subgroup 0 there are now 13, 5 more than before therapy. After therapy, these 13 patients no longer showed any symptoms of depression. The psycho-emotional state of a total of 13 patients changed after the therapy in the direction of improvement - reduction of symptoms of anxiety and depression for patients from EG2 as well.

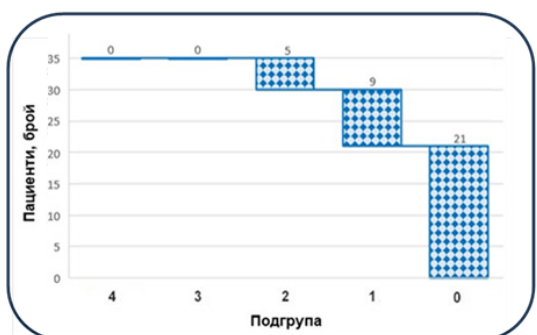
Three months after the therapy in EG2, there are no patients with severe depression, there are two with moderate, and out of five, only 1 patient has mild depression (subgroup 2). Most of the patients (22) were in subgroup 0, without symptoms of depression.

The distribution of depression symptoms 3 months after therapy for EG1 and EG2 is comparable – 23 in subgroup 0 and 8 in subgroup 1 (EG1), respectively 22 in subgroup 0 and 10 in subgroup 1 (EG2).

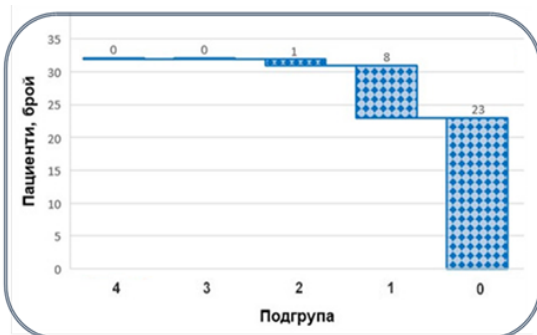
EG1



Before therapy



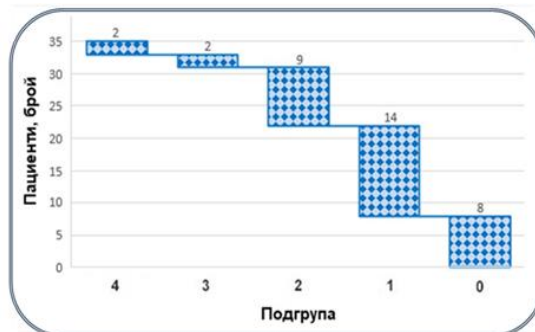
After therapy



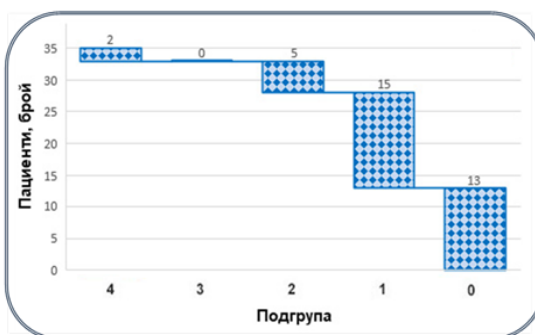
Three months after therapy

Diagram 24. Distribution of patients in EG1 by PHQ-subgroups

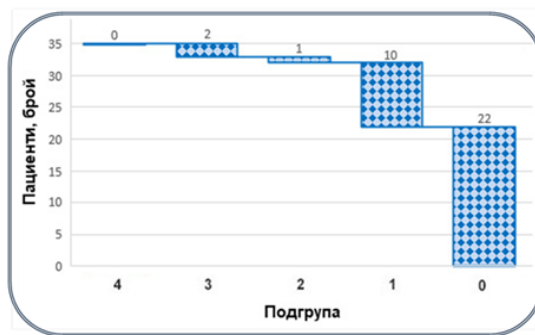
EG2



Before therapy



After therapy



Three months after therapy

Diagram 25. Distribution of patients in EG2 by PHQ-subgroups

3.2. Nonparametric methods

Analysis of tracked subjective and objective variables by Wilcoxon Test

The non-parametric Wilcoxon Signed Ranks Test was used. The test is traditional in comparing the distributions of variables in two related samples. It is applicable to variables with at least an ordinal distribution.

The Wilcoxon test was applied to establish relationships between variables over time. All variables except those with a dichotomous distribution were examined.

The test was administered for Pain (Pn), Cervical Disability Index (NDI) and Psycho-Emotional Status Questionnaire (PHQ-9) and also for the measured variables - Rotation through right/left chin-acromion distance (CAD_R, CAD_L), Lateroflexion via right/left ear-acromion distance (EAD_R, EAD_L), Cervical flexion-extension via chin-sternum distance (CSD) and Total spine mobility via index-under distance (IPD).

Compared were:

- the "*Immediately after therapy*" values (XXX_1) with the values "*Before therapy*" (XXX_0),
- the values "*Three months after therapy*" (XXX_3) with values "*Immediately after therapy*" (XXX_1),
- the values "*Three months after therapy*" (XXX_3) with the values "*Before therapy*" (XXX_0).

The research was done separately for each Experimental Group.

The Wilcoxon test is essentially a hypothesis test.

The null hypothesis H₀ is that there is no statistically significant difference between the two compared values (the next values in the two related samples), i.e. any differences are due to random factors and not to any pattern or trend.

Alternative H₁ is that the differences (regardless of which direction) are statistically significant.

How should we interpret the results?

If $p < 0.05$ – we reject H₀, i.e., the influence of the conducted therapy on the value of the indicator is statistically significant. In which direction this influence is - positive or negative - we learn by comparing the average values.

If $p \geq 0.05$ – we have no statistically significant grounds to reject H₀, i.e., the therapy did not have a significant impact on the value of the indicator.

The results of the Wilcoxon test can be used to suggest two things: the procedures (FT and FT combined with psychological impact procedures) have an effect that is maintained or improved over a 3-month period. Metrics are defined so that decreasing their values is the desired result.

As can be seen from Table 5, the conducted therapy for EG1 had a statistically significant impact on the indicators Pain, Disability in the cervical region, Psychoemotional state after completion of the physiotherapy treatment. Regarding mobility in the cervical region, we have a statistically significant effect on head rotations to the right/left and lateroflexion. There was also an improvement in overall spinal mobility as measured by the sub-index test. For all these indicators $p < 0.05$. Without a significant change from FT is the extension in the cervical lobe ($p = 0.593$).

The therapy carried out for EG2 also had a statistically significant effect after the completion of the course of physiotherapy treatment, both on the indicators Pain, Disability in the cervical region, Psycho-emotional state (Pn, NDI, PHQ-9) and on head rotations to the right/ left (CAD_R/L) and lateroflexion (EAD_R/L) as $p < 0.05$ for these parameters. Total spinal mobility by the Index-Pod test for these patients also improved after completion of the FT course. Regarding the extension in the cervical lobe, there was no statistically significant effect after the applied therapy for these patients either, as $p=0.165 > 0.05$. (Table 6)

The analysis of the indicators from the second pair - "Three months after the therapy" - "Immediately after the therapy" - that the therapy carried out in EG1 had a statistically significant impact on the indicators Pain, Disability in the cervical region, Psycho-emotional state (Pn, NDI, PHQ- 9), at the follow-up 3 months after the end of therapy. Regarding cervical mobility in all planes, there was no statistically significant change in results 3 months after therapy, i.e. what has been achieved is maintained (Table 7).

The conducted therapy for EG2 also had a statistically significant effect on the indicators Pain, Disability in the cervical lobe, Psycho-emotional state (Pn, NDI, PHQ-9), at the follow-up 3 months after the end of the therapy. Regarding mobility in the cervical region, in contrast to EG1, here there is a statistically significant change in the results 3 months after therapy for right/left lateroflexion and right/left rotations. Regarding the extension in the cervical lobe and the mobility of the spine by the Index-Pod test, there was no statistically significant change 3 months after the applied therapy, as $p \geq 0.05$. i.e. what was achieved is retained. (Table 8).

A Wilcoxon test was also applied to compare the values of the variables "Three months after therapy" with the values "Before therapy" in the patients of EG1 and EG2. The results are shown in Tables 9 and 10.

The EG1 therapy performed had a statistically significant effect on all indicators when comparing the results before therapy with those 3 months after therapy. An exception is the extension in the cervical lobe, since $p=0.275$ (Table 9).

Treatment for EG2 also had a statistically significant effect on all measures when comparing the results before therapy with those three months after therapy. An exception is the extension in the cervical lobe since $p = 0.231$ (Table 10).

Analysis of variables with dichotomous distribution by McNemar Test

For all dichotomous variables, McNemar's test was applied, a typical before-after paired-samples test for variables expressed on a dichotomous scale (with only two possible outcomes).

McNemar's test can be used to determine whether there are significant differences between the results of the first ("before") and the second ("after") measurements/records.

In the present work, McNemar's test was applied for the presence or absence of Headache (HA), Vertigo (Vrt), Numbness of upper limbs (Form). Research has been done for the three possible pairs:

- *"Before Therapy" & "After Therapy"*
- *"After therapy" & "3 months after therapy"*
- *"Before therapy" & "3 months after therapy"*

The values registered for patients from EG1 and EG2 were tested separately.

The null hypothesis states:

H0: The value of the variable does not depend on when the registration/measurement is made.

The classic alternative hypothesis is:

H1: The difference between the values of the variable at the two time points is statistically significant.

The classical alternative hypothesis suggests a two-sided critical region. In studies of the present type, when it is clear a priori that the administered therapy either does not affect or positively affects (medically speaking) the outcomes, one can move to a one-sided critical region. In this case, the significance level (p-value) calculated by the test is divided by 2.

The results of applying McNemar's test suggest a significant number – 3 (variables) x 3 (pairs) x 2 (experimental groups) = 18 cross-tabulations. Plus as many tables with the final test results.

In order to reduce this volume of tables to acceptable values, all tables relating to one variable were combined into a kind of summary table. This allowed the reduction of the 36 individual tables to 6 aggregate tables - 3 for each Experimental Group. This obviously necessitates a closer look at the structure and content of the pivot table.

Each summary table (see Tables 11–16 later in the text) includes three cross-tabulations comparing the values of one variable (HA, Vtr or Form) in one of the two groups (EG1 or EG2) recorded at different times. The corresponding crosstabs are located at the top of the summary table - the "**Crosstabs**" section - with each crosstab separated by a double line.

The second part of the summary table - the "**Test Statistics**" section - includes the results of the three McNemar tests, each located below the crosstab to which a pair refers.

The following terms are used in Tables 11–16:

Crosstabs – (Contingency tables) - the meaning and content of the term is explained above;

Test Statistics - The test statistics from McNemar's test

N – Number of patients in the group for whom there are values at both time points

Exact Sig (2-tales) – Statistical significance (two-tailed)

Table 11. McNemar's test - comparing Headache (HA) of EG1 patients at different times

Crosstabs

HA_0 & HA_1			HA_1 & HA_3			HA_0 & HA_3		
HA_0	HA_1		HA_1	HA_3		HA_0	HA_3	
	He	Да		He	Да		He	Да
He	15	0	He	25	0	He	14	0
Да	13	7	Да	4	3	Да	15	3

Test Statistics

N	35	N	32	N	32
Exact Sig. (2-tailed)	0,000	Exact Sig. (2-tailed)	0,125	Exact Sig. (2-tailed)	0,000

For EG1 in the joint examination of HA_0 (Headache before therapy) and HA_1 (Headache immediately after therapy), the null hypothesis is rejected ($p = 0.000 < 0.05$), i.e. headache depends on when it is measured (assessed);

In the joint examination of HA_1 (Headache after therapy) and HA_3 (Headache 3 months after therapy), the null hypothesis is not rejected ($p = 0.125 > 0.05$), i.e. headache did not depend on whether it was measured immediately after therapy or 3 months later. In this case, we may consider that even after 3 months the headache is the same as after the therapy.

3.3. Parametric methods

Checking for normality of the distribution of indicators

The classic Kolmogorov-Smirnov Test was applied to investigate the normality of the distribution of values. With this test we check whether the actual distribution corresponds to the normal. Deviation from normal distribution is considered significant at $p \text{ values} < 0.05$ (*Asymp. Sig. (2-tailed) < 0.05*).

All indicators were tested, except those with a dichotomous distribution. For all tested indicators in EG1 and EG2, $p > 0.05$, that is, the probability of error is not significant. This allows us to conclude that these variables obey the normal distribution well enough and can be used in parametric studies, for example, various Parametric tests, Dispersion, Correlation and Regression analysis. Detailed results can be seen in Tables 17 and 18.

Table 18 are the results of the application of the Kolmogorov-Smirnov Test for normality for the monitored indicators in the patients from EG2:

Comparing the averages of all tracked metrics by Independent Samples t-Test

A comparison was made of the average values of all tracked indicators for the two experimental groups with a normal or close to normal distribution at the three times of registration. In other words, the test was applied to each variable that successfully passed the Kolmogorov-Smirnov test.

Tables 19 and 20 contain the results of comparing the mean values of the subjective and objective indicators between the two experimental groups. From these it can be seen that there is no great difference between the average values in the two groups. For example, for the indicator Pn (Pain) we can say that the difference between the values shows that in EG1 the decrease after the therapy compared to before the therapy is 2.86 points, or by 47%, then in EG2 the decrease is by 3.10 points or 48%. How significant or not these differences in the mean and variance are, we understand from Table 21.

Traditionally, in the test output (SPSS) table, there are two rows for each variable, for example:

		Levene's Test for Equality of Variances		t-test for Equality of Means				
		F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference
Pn_0	Equal variances assumed	,026	,873	-,940	68	,351	-,4571	,4866
	Equal variances not assumed			-,940	67,881	,351	-,4571	,4866

As can be seen, Levene's test for equality (homogeneity) of variances shows that the variances of the distributions in the two groups do not differ statistically significantly ($p = 0.873$; $p > 0.05$), therefore, the application of the t-test is correct. In the present study, this was true for all variables. For this reason, the second row from the table - "Equal variances not assumed" ("Variances are not assumed to be equal") for all variables has been removed.

The test shows that the two groups are correctly selected, i.e. random way and there is no hidden reason for the equality of the means in the two groups.

Comparing group means using the Paired Samples Test (t-test for paired samples)

Paired Samples Test is used to analyse two related samples. The three pairs of related samples are analyzed - "*Before therapy* ⇔ *Immediately after therapy*"; "*Immediately after therapy* ⇔ *Three months after therapy*"; "*Before therapy*" ⇔ *Three months after therapy*". The test was applied separately for the two experimental groups.

As can be seen from Table 22, for the subjective indicators in all pairs, there is a decrease in the value of the variable at the second position, i.e. after therapy (XXX_1) vs. value before therapy (XXX_0); three months after therapy (XXX_3) versus values after the end of therapy (XXX_1); three months after therapy (XXX_3) compared to values at the beginning of therapy (XXX_0). This implies success of the therapy and also possible maintenance and improvement of the values within 3 months after the therapy. But whether these differences are statistically significant or the result of random deviation becomes clear after the complete implementation of the test.

The same is observed with the objective indicators (measured in cm) (Table 23) – in all pairs there is a decrease in the value of the variable at the second position, i.e. after therapy (XXX_1) vs. value before therapy (XXX_0); three months after therapy (XXX_3) versus values after the end of therapy

(XXX_1); three months after therapy (XXX_3) compared to values at the beginning of therapy (XXX_0). This again implies both the success of the therapy and the maintenance and improvement of the values within 3 months after the therapy. But again, we will find out if these differences are statistically significant after the full implementation of the test.

Table 24 shows the correlation between the variables in each of the analysed pairs. In all pairs, the correlation is high and, moreover, statistically significant (everywhere $p < 0.0005$). The only exception is the pair Pn_0 & Pn_3, where $p = 0.002$ (ie, 0.2%!).

The result of applying the t-test to compare the means in each pair of related samples in EG1 is shown in Table 25:

Table 25. t-test for comparison of means in each pair of related samples in EG1

Pair		Paired Differences					t	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
					Lower	Upper			
1	Pn_0 - Pn_1	2,8571	1,6296	,2754	2,2974	3,4169	10,373	34	,000
2	Pn_1 - Pn_3	1,0625	1,4577	,2577	,5369	1,5881	4,123	31	,000
3	Pn_0 - Pn_3	3,9688	1,8047	,3190	3,3181	4,6194	12,440	31	,000
-									
19	EAD_L_0 - EAD_L_1	1,229	2,961	,501	,211	2,246	2,454	34	,019
20	EAD_L_1 - EAD_L_3	,063	1,105	,195	-,336	,461	,320	31	,751
21	EAD_L_0 - EAD_L_3	1,344	3,065	,542	,239	2,449	2,480	31	,019

The analysis of the test results is not difficult - the corresponding p -value (Sig. (2-tailed)) shows whether the difference between the average values of the indicators in the pair (in fact, of the indicator at two different moments) are statistically significantly different. In this case, all values except those coloured red are with $p < 0.05$, which means that the means are different. Whether they became smaller or larger can be seen from the average values themselves (Tables 22–23). Thus, we confirm what was said after the two descriptive tables.

An analogous comparative analysis of the average values for each pair of related samples in EG2, for the subjective and objective indicators, was made, presented in Tables 26 and 27. And in EG2, we find an improvement in the results in the second moment for each pair. The conclusion about randomness or regularity of these results is made after the full implementation of the test.

In both EG1 and EG2, we find a strong and significant correlation when comparing the mean values of the variables in each pair of related samples.

The result of applying the t-test to compare the means in each pair of related samples in EG2 is shown in Table 29. This table deserves to be included in full, but we will content ourselves with just commenting on it.

In EG2 the results are significantly better than those in EG1. This time there is not a single pair for which we cannot claim that the difference between the means is statistically significant – $p < 0.05$ everywhere. And if we exclude pairs 11, 14, 17 and 20 - all of the type "After therapy - Three months after therapy", for all the remaining 17 pairs $p < 0.0005!$

Again, to ascertain the direction of change, we must refer to Tables 26 27 and compare the means. Thus, we find that there is an improvement in values for all pairs.

With the help of the t-test for related samples, we found that, with small exceptions observed in EG1, the applied therapies improved the condition of patients from both groups. The question arises as to which of the two therapies is more effective.

A successful way of constructing samples allows us to combine related and independent samples. Since in linked samples there is a one-to-one reciprocal correspondence between the elements of the two samples – in other words, the pair of linked samples only includes patients for whom exactly one value is recorded at both time points – the difference between the values can be calculated. We treat these differences as the values of a new, derivative variable in the second sample of the linked pair. Furthermore, for each measure it holds that the difference between the means in the related samples is equal to the mean of the differences of the corresponding values in the individual patients.

To comprehensively answer the question of whether one therapy is more effective than the other, we compare the changes in mean values in analogous (“identical”) pairs in the two experimental groups. The result of the comparison is shown in the following Table 30:

Table 30. Comparison of changes in mean values
in each corresponding pair of related samples from EG1 and EG2

Pair of variables		Change in mean		Advantage:
		EG1	EG2	
1	Pn_0 - Pn_1	-2,857	-3,100	EG2
2	Pn_1 - Pn_3	-1,063	-1,300	EG2
3	Pn_0 - Pn_3	-3,969	-4,400	EG2
4	NDI_0 - NDI_1	-4,400	-3,829	EG1
5	NDI_1 - NDI_3	-1,969	-2,486	EG2
6	NDI_0 - NDI_3	-6,250	-6,314	EG2
7	PHQ_0 - PHQ_1	-2,143	-2,143	====
8	PHQ_1 - PHQ_3	-1,344	-1,686	EG2
9	PHQ_0 - PHQ_3	-3,438	-3,829	EG2
10	CAD_R_0 - CAD_R_1	-0,829	-1,086	EG2
11	CAD_R_1 - CAD_R_3	-0,406	-0,457	EG2
12	CAD_R_0 - CAD_R_3	-1,313	-1,543	EG2
13	CAD_L_0 - CAD_L_1	-0,857	-0,829	EG1
14	CAD_L_1 - CAD_L_3	-0,094	-0,514	EG2
15	CAD_L_0 - CAD_L_3	-1,031	-1,343	EG2
16	EAD_R_0 - EAD_R_1	-0,886	-0,957	EG2
17	EAD_R_1 - EAD_R_3	-0,313	-0,400	EG2
18	EAD_R_0 - EAD_R_3	-1,250	-1,357	EG2
19	EAD_L_0 - EAD_L_1	-1,229	-0,771	EG1
20	EAD_L_1 - EAD_L_3	-0,063	-0,571	EG2
21	EAD_L_0 - EAD_L_3	-1,344	-1,343	====

In the columns labelled "EG1" and "EG2" are shown the changes recorded in the average values in the respective Experimental Group.

The table shows which of the two therapies is superior. (We recall that a smaller value indicates a better effect of the respective therapy). As can be seen, the therapy administered in Experimental Group 2 had an advantage in 16 out of 21 pairs; the one applied in EG1 – in 3 pairs; in two of the cases, we have a tie. At the same time, the advantage of EG1, where it is registered, is minimal – in pair No. 4 (NDI_0 – NDI_1) the advantage is 0.57 points, and in pairs No. 13 (CAD_L_0 – CAD_L_1) and No. 19 (EAD_L_0 – EAD_L_1) the difference is 0.029 cm and 0.457 cm respectively.

The results on which Table 30 is based are illustrated in Figures 29 and 30.

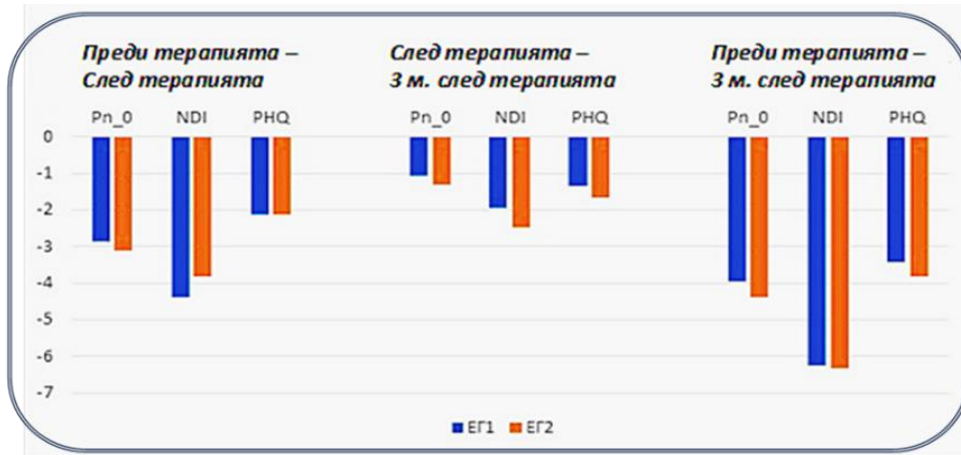


Chart 29. Comparing changes in mean values in each respective pair of connected samples from EG1 and EG2 – subjective indicators

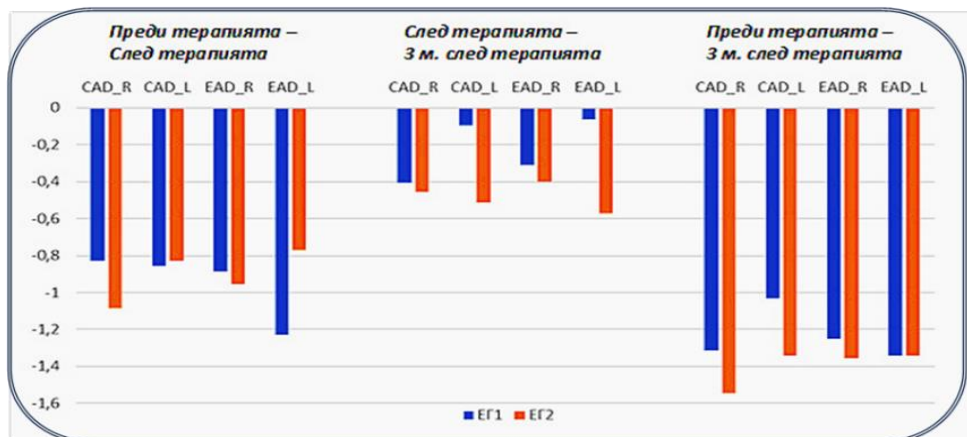


Chart 30. Comparing changes in mean values in each respective pair of connected samples from EG1 and EG2 – objective indicators

In conclusion – the results of the application of the parametric t-test give reason to conclude that the combined therapy applied in Experimental Group 2 has a slight but sustainable advantage over that applied in Experimental Group 1.

3.4. Correlation analysis between variables

We determine the strength of the relationship between the values of the variables within the group at different points in the study. As shown above, all variables (except those with a dichotomous distribution) satisfy the requirements of the Kolmogorov-Smirnov test for normality. The Pearson Correlation coefficient was calculated using IBM SPSS.

The correlation between the values of the variables in pairs, at different points in time, separately for the two groups, was examined. The results can be seen in Tables 32 and 33 of the dissertation.

In all tables, the correlation coefficient is followed by a ** sign, which means, according to IBM SPSS, that the correlation is significant at the 0.01 level (2-tailed) instead of the standard 0.05 level. (**. Correlation is significant at the 0.01 level (2-tailed).

It is interesting to compare correlation coefficients for variables of the same name for the same pair over time. Since, as we understand, there is no problem with the significance level, we may omit this metric from the pivot table. The result is shown in the following Table 33:

Table 33. The Pearson correlation. Performance Test in patients from EG1 and EG2 for the three pairs

	преди терапията – след терапията		преди терапията – 3 мес. след терапията		след терапията – 3 мес. след терапията	
	EG1	EG2	EG1	EG2	EG1	EG2
Pn	,658**	,765**	,523**	,526**	,671**	,640**
NDI	,752**	,923**	,742**	,753**	,872**	,798**
PHQ	,927**	,952**	,796**	,860**	,861**	,928**
CAD_R	,857**	,928**	,785**	,836**	,851**	,899**
CAD_L	,751**	,940**	,841**	,851**	,843**	,901**
EAD_R	,865**	,962**	,839**	,929**	,945**	,941**
EAD_L	,661**	,943**	,624**	,879**	,957**	,909**
CSD	,979**	,964**	,942**	,909**	,965**	,947**
IPD	,894**	,977**	,873**	,968**	,969**	,991**

Cross-correlation analysis between subjective variables - Pain (Pn), Cervical Disability Index (NDI) and the Psycho-Emotional Status Questionnaire (PHQ-9)

The dissertation presents six scatter diagrams, divided into two groups - EG1 (Diagrams 31-33) and EG2 (Diagrams 34-36) - before therapy; after therapy; three months after therapy. In each scatterplot, the triplet variables Pn, NDI, and PHQ are shown.

Each of the diagrams is preceded by a pair of tables. The descriptive tables (Descriptive) show the values of the arithmetic mean (Mean) and the standard deviation (Std. Deviation), as well as the number of observations (N) - the number of patients for whom the values were registered (Tables 34, 36 and 38 - EG1; 40, 42, 44 - EG2).

The correlation tables (Correlations) show the value of the correlation coefficient between the indicators (Pearson Correlation) and the corresponding level of significance (Sig. (2-tailed)) for each pair of indicators (Tables 35, 37 and 39 - EG1; 41, 43, 45 - EG2).

The charts contain the scatterplots for each ordered pair of the three metrics. The pointer, which is indicated on the left, on the corresponding row, is located along the ordinate (y-axis). The indicator indicated at the bottom of the diagram is located along the abscissa (x-axis).

It is interesting to follow the correlation between the three indicators in EG2 due to the formulated hypothesis that there are changes in the psycho-emotional state of the patients and there is a correlation between the influence and the other symptoms.

Table 40. Descriptive statistics – EG2; before therapy

	Mean	Std. Deviation	N
Pn_0	6,486	2,0775	35
NDI_0	14,23	6,413	35
PHQ_0	8,77	5,117	35

Table 41. Correlations – EG2; before therapy

		Pn_0	NDI_0	PHQ_0
Pn_0	Pearson Correlation	1	,142	-,161
	Sig. (2-tailed)		,417	,356
NDI_0	Pearson Correlation	,142	1	,461**
	Sig. (2-tailed)	,417		,005
PHQ_0	Pearson Correlation	-,161	,461**	1
	Sig. (2-tailed)	,356	,005	

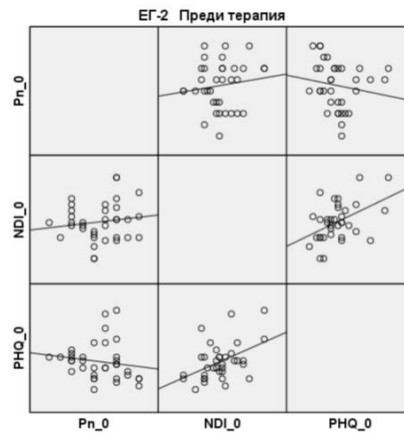


Diagram 34. Scatter diagrams – EG2; before therapy

The Pearson correlation coefficient for the pair PHQ_0 – NDI_0 before therapy shows moderate dependence (0.461) (Chart 34).

Correlation between the three indicators in EG2 - after the therapy

Table 42. Descriptive statistics – EG2; after therapy

	Mean	Std. Deviation	N
Pn_1	3,386	1,9781	35
NDI_1	10,40	5,569	35
PHQ_1	6,63	4,747	35

Table 42. Correlations – EG2; after therapy

		Pn_1	NDI_1	PHQ_1
Pn_1	Pearson Correlation	1	,342*	-,106
	Sig. (2-tailed)		,044	,543
NDI_1	Pearson Correlation	,342*	1	,564**
	Sig. (2-tailed)	,044		,000
PHQ_1	Pearson Correlation	-,106	,564**	1
	Sig. (2-tailed)	,543	,000	

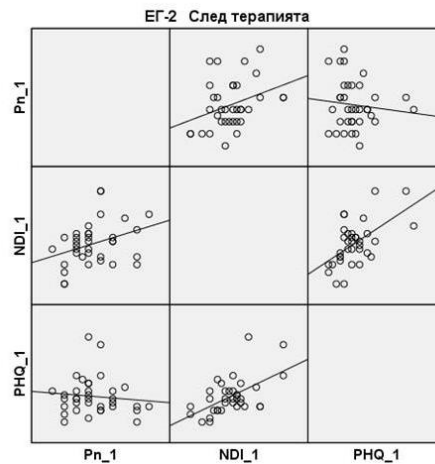


Diagram 35. Scatter diagrams – EG2; after therapy

After therapy, the Pearson correlation coefficient for the pair PHQ_1–NDI_1 showed a moderate dependence (0.564). The Pearson correlation coefficient for the Pn–NDI pair increased slightly from 0.142 to 0.342. (Diagram 35).

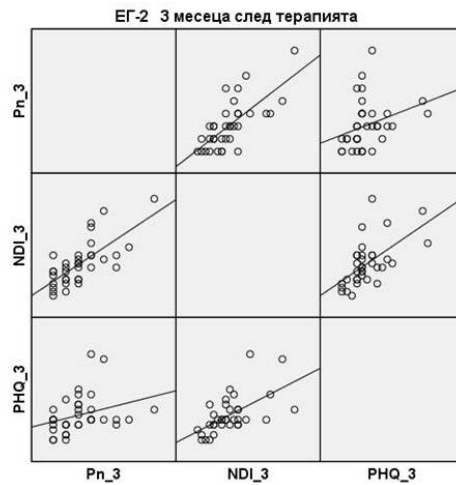
Correlation between the three indicators in EG2 – three months after the therapy

Table 44. Descriptive statistics – EG2; three months after therapy

	Mean	Std. Deviation	N
Pn_3	2,086	1,9000	35
NDI_3	7,91	5,506	35
PHQ_3	4,94	3,819	35

Table 45. Correlations – EG2; three months after therapy

		Pn_3	NDI_3	PHQ_3
Pn_3	Pearson Correlation	1	,718**	,313
	Sig. (2-tailed)		,000	,067
NDI_3	Pearson Correlation	,718**	1	,594**
	Sig. (2-tailed)	,000		,000
PHQ_3	Pearson Correlation	,313	,594**	1
	Sig. (2-tailed)	,067	,000	



The Pearson correlation coefficient for the pair PHQ_3–NDI_3 moderate dependence (0.594). The increase in Pearson's coefficient for Pn–NDI already shows a high dependence 3m after therapy (0.718). (Diagram 36)

The interpretation of the results is done in accordance with the correlation degree data:

Positive correlation	Negative correlation	The dependence is:
$0.0 \leq r < 0.3$	$-0.3 < r \leq 0.0$	weak
$0.3 \leq r < 0.5$	$-0.5 < r \leq -0.3$	moderate
$0.5 \leq r < 0.7$	$-0.7 < r \leq -0.5$	significant
$0.7 \leq r < 0.9$	$-0.9 < r \leq -0.7$	strong
$0.9 \leq r$	$r \leq -0.9$	very strong

3.5. Regression analysis (ANOVA)

If the correlation calculation characterizes the strength and direction of the relationship between two variables, then the regression analysis serves to determine the type of this relationship and makes it possible to predict the values of one (dependent) variable, based on the values of the other (explanatory, independent) variable.

Variables that successfully passed the Kolmogorov-Smirnov test for normality of distribution were examined: both the subjective variables Pain (Pn), Cervical Disability Index (NDI), the Psycho-Emotional Status Questionnaire (PHQ-9), and the objective variables –Rotation via right/left chin-acromion distance (CAD_R, CAD_L), Lateroflexion via right/left ear-acromion distance (EAD_R, EAD_L), Cervical flexion-extension via chin-sternum distance (CSD) and Total spinal mobility by the index-under distance (IPD).

The study covers the two Experimental groups and for each of them – the three moments of recording the values of the indicators.

The statistical tool "Linear regression analysis" (ANOVA) used allows to measure the magnitude of the dependence between a variable and the outcome of interest, fixing the action of all other factors. In this way, we can single out the influence of one variable while holding constant the effect of the other variables.

Another important indicator, besides the correlation coefficient R , is the coefficient of determination R^2 . While R indicates the strength of the relationship between the dependent and independent variable, the coefficient of determination R^2 indicates how much of the value of the dependent variable is explained by the value of the independent (explanatory) variable. The remaining part (up to 100%) of the value of the outcome variable (in this case – the value after therapy) is determined by other factors.

The following two tables show the correlation and determination coefficients in the two groups for the three pairs over time:

Table 46 and 47 Pearson Correlation. Values of R and R² for indicators in the patients of the two groups for the three possible pairs over time: before FT; immediately after FT; 3 months after therapy

EG1

EG2

	before therapy – after the therapy		before the therapy – 3 months after the therapy		after the therapy – 3 months after therapy	
	R	R ²	R	R ²	R	R ²
Pn	,658	43%	,523	27%	,671	45%
NDI	,752	57%	,742	55%	,872	76%
PHQ	,927	86%	,796	63%	,861	74%
CAD_R	,857	73%	,785	62%	,851	72%
CAD_L	,751	56%	,841	71%	,843	71%
EAD_R	,865	75%	,839	70%	,945	89%
EAD_L	,661	44%	,624	39%	,957	92%
CSD	,979	96%	,942	89%	,965	93%
IPD	,894	80%	,873	76%	,969	94%

	before therapy – after the therapy		before the therapy – 3 months after the therapy		after the therapy – 3 months after therapy	
	R	R ²	R	R ²	R	R ²
Pn	,765	59%	,526	28%	,640	41%
NDI	,923	85%	,753	57%	,798	64%
PHQ	,952	91%	,860	74%	,928	86%
CAD_R	,928	86%	,836	70%	,899	81%
CAD_L	,940	88%	,851	72%	,901	81%
EAD_R	,962	93%	,929	86%	,941	89%
EAD_L	,943	89%	,879	77%	,909	83%
CSD	,964	93%	,909	83%	,947	90%
IPD	,977	95%	,968	94%	,991	98%

The Pearson correlation coefficient was high for all tracked variables for both EG1 and EG2. The coefficient of determination R² was high immediately after the physical therapy course, being percentage-wise higher for almost all tracked variables in the EG2 patients.

Plots are plotted and correlation clouds and regression lines “connecting” pre-therapy values (XXX₀) to post-therapy values (XXX₁) are shown for EG1 and EG2, respectively. Correlation and regression analysis (Charts 37–43) essentially use the results illustrated in Charts 5–11.

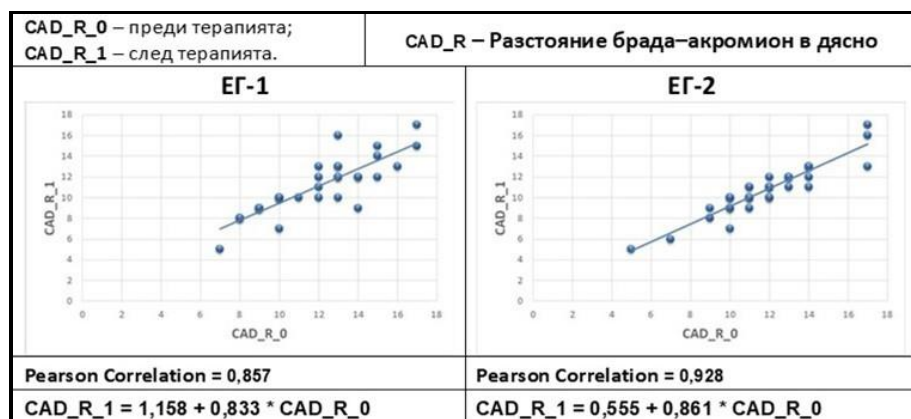


Diagram 40. Rotation - chin-acromion distance on the right - diagrams of the scatter and correlation lines for the two groups EG1 and EG2

Pearson correlation coefficients were higher for **right rotations** for EG2 patients. (Diagram 40). From here, the coefficient of determination in this group reaches 86% – compared to 73% in EG1.

What is interesting in this case is the almost identical characteristics of the two groups of patients, both before and after therapy. The arithmetic mean before therapy was 11.9 cm in EG1 and 11.8 cm in

EG2; after therapy – 11.1 and 10.7 cm, respectively. The median before therapy was 12.0 cm in both groups, after therapy – 10.0 and 11.0 cm. And the maximum value was 17.0 cm, as before, and after therapy, regardless of group.

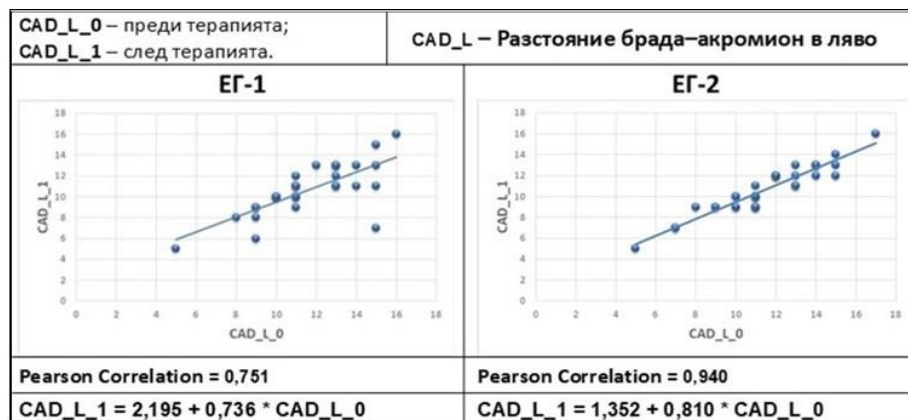


Diagram 41. Rotation - chin-acromion distance on the left - diagrams of the scatter and correlation lines for the two groups EG1 and EG2

The Pearson correlation coefficient was higher for **left rotations** for EG2 patients – 0.940 versus 0.715 in EG1. (Diagram 41). Thus, the coefficient of determination in EG2 reaches 88% against 56% in EG1.

And for left rotations, almost identical characteristics were observed in both groups of patients, both before and after therapy. The arithmetic mean before therapy was 11.6 cm in EG1 and 11.5 cm in EG2; after the therapy – 10.7 cm in both groups. The median before therapy was 11.0 cm in both groups, after therapy – 11.0 and 10.0 cm. And the maximum value was 16.0 cm, with one exception – 17.0 cm before therapy in EG2.

Examination of the correlation and linear regression for **right lateroflexion** shows a pattern analogous to that observed for right and left rotations. The Pearson correlation coefficient was higher for lateroflexion to the right for EG2 patients – 0.962 versus 0.865 in EG1. (Diagram 42). Thus, the coefficient of determination in EG2 reaches 93% against 75% in EG1.

Correlation cloud plots and regression lines were also constructed for the subjective variables. The Pearson correlation coefficient for the PHQ was 0.927 for EG1 and 0.952 for EG2. (Diagram 39). These are high values for both groups, indicating a very strong correlation. This also leads to high values of the coefficient of determination - 86% and 91%, respectively for EG1 and EG2. The correlation between pain values before and after therapy ((Pn_0 and Pn_1) is stronger in EG2 (0.765) than in EG1 (0.658). (Diagram 37). The conclusion is similar for the Pearson correlation coefficient for NDI - higher in EG2 (0.923), compared to 0.752 for EG1 (Chart 38).

Linear regression analysis (MANOVA) by sex

The previous chapter discussed the use of univariate regression analysis to relate in the Regression Equation (linear regression) the values of indicators after therapy with the values of the same indicators before therapy. The ANOVA procedure was used.

On the variables Pain (Pn), Cervical Disability Index (NDI), Psycho-Emotional Status Questionnaire (PHQ-9), a Multifactor Analysis (MANOVA) with included dummy variable Gender was applied. The Cervical Disability Index (NDI) variable was used as an example.

The linear regression equation connecting the variables NDI_1 and NDI_0 has the form

$$NDI_1 = a + b \cdot NDI_0$$

NDI_1 is the dependent variable, NDI_0 – the explanatory (independent) variable. The coefficient b in front of the independent variable is a regression coefficient.

For EG1, the regression equation connecting NDI_1 and NDI_0 has the form

$$NDI_1 = -0.929 + 0.755 \cdot NDI_0 ; R = 0.752 ; R^2 = 56.5\% ; \text{Sign.} = 0.000$$

The equation shows a strong positive relationship between NDI_1 and NDI_0 , and that as a result of therapy, each initial (before therapy) point is reduced to 0.755 points (points decrease by 24.5%).

In EG2, things look like this:

$$NDI_1 = -1.006 + 0.802 \cdot NDI_0 ; R = 0.923 \text{ and } R^2 = 85.2\% \text{ Sign.} = 0.000$$

In EG2, the relationship of therapy results to pre-therapy values is almost functional. The coefficient of determination R^2 is significantly higher for EG2 – 85.2% compared to 56.5% for EG1.

Let's include gender in the consideration, ie. to examine whether patient gender affects dependence. For this purpose, we use the dummy variable Dm_Sex , which has a value of 0 if the patient is male and 1 if the patient is female. In this case, the regression equation takes the form

$$NDI_1 = a + b \cdot NDI_0 + d \text{ (if Sex=2)}$$

The coefficient d in front of the dummy variable can be interpreted as the influence on the NDI_1 value of the fact that the patient is female, *ceteris paribus*.

We now use MANOVA - Multifactor Analysis - and get:

At EG1:
$$NDI_1 = -1.558 + 0.717 \cdot NDI_0 + 1.640 \text{ (if Sex=2)}$$

at $R = 0.763 ; R^2 = 58.2\% ; \text{Sign.} = 0.000$

In EG2 the result is different:

$$NDI_1 = -0.546 + 0.824 \cdot NDI_0 - 1.004 \text{ (if Sex=2)}$$

at $R = 0.926 ; R^2 = 85.7\% ; \text{Sign.} = 0.000$

Note: in EG1, each point of *NDI_0* is reduced to 0.717 points in *NDI_1*. In EG2, this reduction is up to 0.824 points for every one point or 0.107 less. With a pre-treatment mean of just over 14 points, the difference in question between the two groups was only 1.5 points on average.

On the other hand, the points for each female patient in EG1 *increased* after therapy by 1.64 points - only "due" to gender. In EG2, the situation is reversed - the score of each female patient is *reduced* because of the therapy by 1.0 point - again only because of gender. In other words, the difference is 2.64 points. We can say that the applied methods of psycho-emotional impact have a stronger impact on women.

In the graphs used, the individual points forming the correlation cloud and describing the male patients are in blue, and those corresponding to the female patients are in red. The corresponding regression lines are coloured in the same colours. There are two diagrams, for EG1 and EG2 respectively.

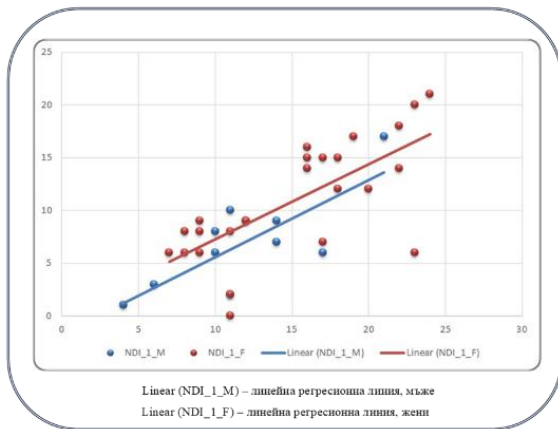


Diagram 44. NDI - correlation lines at EG1 depending on gender

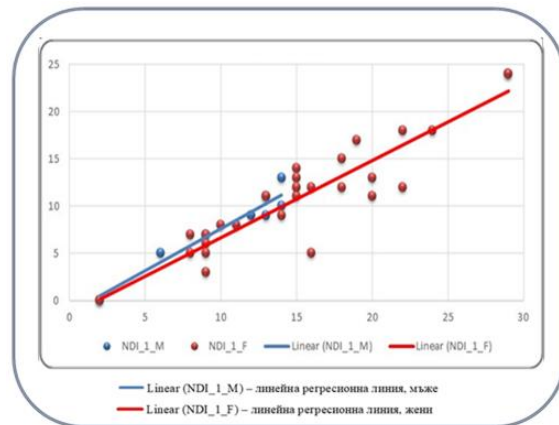


Diagram 45. NDI - correlation lines at EG2 depending on gender

Regarding the Cervical Disability Index, the therapy slightly lowers the values in women from EG1. (Diagram 44).

Regarding the Cervical Disability Index, the therapy lowers the values to a greater extent in women from EG2. (Diagram 45).

What has been shown so far is not only observed for NDI. The described procedures were applied to the Pn, NDI, and PHQ indices and the corresponding regression equations were obtained relating the pre-therapy values to the post-therapy results.

4. DISCUSSION

Pain is a widespread medical problem that has not only individual but also social and economic consequences. It is a challenge to better understand both the etiological and risk factors for the occurrence of pain, as well as to enrich the approach to its influence and treatment. Statistically, musculoskeletal pain is one of the most common reasons for seeking medical services in Western societies [65, 166], with neck or low back pain accounting for the majority of all musculoskeletal disorders [140]. They are characterized by frequent relapses and chronification of complaints, which lead to a change in the psycho-emotional state of the patients.

Pain is a widespread medical problem that has not only individual but also social and economic consequences. It is a challenge to better understand both the etiological and risk factors for the occurrence of pain, as well as to enrich the approach to its influence and treatment. Statistically, musculoskeletal pain is one of the most common reasons for seeking medical services in Western societies [65, 166], with neck or low back pain accounting for the majority of all musculoskeletal disorders [140]. They are characterized by frequent relapses and chronification of complaints, which lead to a change in the psycho-emotional state of the patients.

As a **first hypothesis** in our study, the presence of a high percentage of risk factors that predispose to chronic pain in the cervical region is assumed. The available risk factors in the patients followed by us were evaluated. One of these studied factors is obesity. Obesity was not detected in the majority of patients from both groups - BMI was normal for 68.6% of patients in EG1 and for 71.4% of EG2. Based on the mean values of BMI and the percentage distribution of the values in the group, we can argue that this risk factor affects the severity of symptoms identically in both groups (Table 3, Histograms 3 and 4). In the literature, data on the influence of obesity on the development of chronic neck pain are conflicting. A recent study - Mork PJ et al, showed that overweight and obesity increased the risk of fibromyalgia during an 11-year follow-up period. However, it is not known whether excess body mass has a similar effect on the risk of localized chronic neck or low back pain [128]. There is evidence from other studies where obesity is associated with an increased risk of chronic neck and low back pain in both women and men. In a large-scale epidemiological study of over 30 thousand people in Norway, Nilsen T.I.L et al. reported that individuals classified as overweight and obese had a higher risk of chronic low back and neck pain than individuals classified as normal weight. Excess body weight is also associated with an increased one-year incidence of neck and shoulder complaints in individuals from a variety of occupations [132, 161]. In conclusion, we can say that recommendations for patients with chronic neck or low back pain should include regular physical exercise and maintaining a normal body weight. We believe that excess body weight is a controllable risk factor for chronic neck pain through a healthy diet and increased physical activity.

When evaluating the presence of old traumas in the cervical region, we can say that this risk factor is not common in the followed patients. The proportion of patients with cervical injuries was too small to result in statistically significant differences in the therapeutic response of patients from the two groups. Among treated patients, the frequency of old injuries was identical for both groups – 22.9% (8 people) from each group (Diagram 3).

When monitoring for the presence of smoking as a risk factor among treated patients, smokers in EG1 were only 17.1% (6 people), and in EG2 – 20.0% (7 people) (Diagram 4). The proportion of smokers in both experimental groups is too small to seek any statistically significant conclusions.

With regard to advanced age as a reason for chronification of complaints of pain in the neck lobe - the results of our study indicate that half of the patients from EG1 are over 54 years old, and respectively over 62 years old for EG2 (Table 1). Only 8 patients from EG1 and 7 from EG2 were aged up to 40 years (Histograms 1 and 2). This coincides with the data from the literature that chronic neck pain is characteristic of older age. In order to influence the frequency of neck pain chronicity with advancing age, it is important to prevent it by educating patients at a younger age.

Gender has also been reported as a risk factor for complaints of persistent neck pain. Statistically, chronic neck pain is more common in women. Gender differences in pain perception have a psychosocial and biological component. Women are more sensitive, more self-focused, and more likely to experience anxiety and depression. Gender differences have also been found in the endogenous opioid system, in some of the pain receptors, and in its perception by internal organs [103]. In our study, the proportion of women in both groups was higher than that of men. Followed patients were 52 women (74.3%) and 18 men (25.7%) for both groups, respectively. The distribution by gender for the two groups is presented in Diagram 1 – women are 25 (71.4%) from EG1 and 27 (77.1%) from EG2. It can be seen that women are more than 2/3 of the observed patients. In our study, we found that the effect on performance in daily activities was different for men and women of both EGs. Women from EG2 had a greater decrease in cervical disability index values after therapy (i.e., improvement in self-care) compared to men from the same group. For patients from EG1, this dependence is reversed – the values of the cervical disability index decrease less in women from EG1 after the therapy. We can say that for the women of EG2, the applied complex therapy combined with an information booklet and exercises for home application is more effective in helping to cope with daily activities compared to the men of the group. (Charts 50 and 51). There is a similar correlation between the influence of Pn, NDI and PHQ indicators depending on gender. Additional studies can specify why women, after applied methods of psycho-emotional impact, significantly improve their results, compared to men.

As a **second hypothesis** in our study, the presence of a change in the psycho-emotional state of patients with chronic neck pain is assumed. On purposeful assessment of the patient using the Psychoemotional Status Questionnaire (PHQ-9), the presence of anxiety and depression was observed in more than half of the patients in both groups. These psychoemotional changes interact with the physical pathology to modulate the symptoms of the patient with cervical osteochondrosis and osteoarthritis. In the individuals followed in our study, these symptoms were present in 62% of patients from EG1 and in 77% from EG2 (Charts 24 and 28). All patients experienced a reduction in symptoms after completion of the FT treatment course and 3 months thereafter. These observations correlate with changes in the psychoemotional state of patients with chronic pain found in a number of other larger studies. In a study conducted in Germany, including 448 patients with chronic back pain, a change in mood was found in forty-eight percent of them [49]. Data from a large-scale Western Australian study of fifteen hundred and eighty participants (mean age 14.1 years) suggest that spinal pain is associated with psychiatric changes in adolescents [144]. These data support the need to consider both psychological and pain symptoms when evaluating and developing a treatment plan for patients with chronic neck pain. In Bulgaria, recommendations to physical medicine specialists for evaluation and influence of psycho-emotional changes in the treatment of such patients are still not commonly applicable and imposed. A large-scale

international study of 24 countries from 2013 (of which Canada has the largest participation - 44%, but without the participation of Bulgaria) on the methods used to evaluate patients with cervical dysfunction, found that most often - at 75 % of respondents – pain assessment (numerical or visual analogue) was used. 381 clinicians treating patients with neck pain - physiotherapists and chiropractors - were surveyed. But the majority of respondents have never tested fear of movement, psychological stress or global assessment of change (less than 10% use them routinely). Respondents frequently used the neck impairment index (49% of them) [94]. The approach to the assessment of cervical dysfunction has evolved in recent years, following the accumulation of studies demonstrating a clear relationship between cervical pain and psychoemotional changes, with anxiety and depression being increasingly sought and assessed [147]. In accordance with these guidelines, in our study we used the PHQ-9 test to assess mood changes. It is quick and reliable, validated for the assessment of symptoms of anxiety and depression [157].

Rehabilitation is a major part of the treatment plan for conservative treatment of chronic cervical pain. The **third hypothesis** was confirmed for the effective functional recovery of the subjects after the application of the developed conventional physiotherapy program, which includes a heat procedure, medium-frequency currents with pain-relieving parameters and kinesitherapy. This effect was assessed by positively affecting pain intensity, mobility in the cervical region, improvement in self-efficacy in performing daily activities (assessed by the Cervical Disability Index - NDI) and the improved psychoemotional state (via the PHQ-9) of followed patients. The improvement in these indicators was more significant immediately after the completion of the FT course, compared to the changes in the indicators 3 months after the therapy.

In terms of pain intensity, patients in both groups saw a significant reduction – by more than 70% – over the follow-up period. Before the therapy, the mean value of pain was 6.0 for patients from EG1 and 6.5 for those from EG2, respectively. The average value of this indicator for EG1 after the therapy is 3.2 points, and accordingly – 3.4 points for EG2. In the short-term follow-up (after the completion of the FT course), the applied therapy reduced the pain intensity by 50% for the patients in both groups. At 3 months post-therapy, the mean pain score for both groups was identical, 2.0 and 2.1. The tendency to reduce pain persists 3 months after the procedures have been completed, i.e. results were sustained for patients in both groups (Chart 5).

In the literature, there is sufficient data on the effectiveness of the application of preformed factors to influence pain symptoms in various musculoskeletal diseases. The goal of physical therapy for chronic cervical pain is to reduce pain, improve the mobility of the spine, which allows the patient to gain sufficient efficiency in his daily activities. Previous studies have shown the benefit of physiotherapy in osteoarthritis. Bulgarian studies reported the use of these factors and proved the analgesic effect of medium frequency currents for neck or low back pain [2, 3]. The use of these non-pharmacological modalities has been questioned by some practitioners. Although this skepticism may be warranted for some alternative pain therapies, there are in fact well-controlled studies confirming the benefits of using electroanalgesia and laser therapy for the management of acute or chronic musculoskeletal pain [6, 142]. Prof. Koleva introduced the term physical analgesia, based on evidence of the effectiveness of preformed factors as an analgesic [13]. However, there is a lack of recent Bulgarian studies on the effectiveness of complex physical therapy for chronic neck pain. Our achieved results provide a good guideline for their successful application in this pathology.

Regarding changes in mobility in the cervical spine, a more significant improvement for patients from both groups was observed immediately after the end of physical therapy. An increase in mobility was observed for rotations and lateroflexion to the right and to the left, as well as spinal mobility measured by the sub-index test. There were no statistically significant changes in the cervical lobe movements in the sagittal plane. All three components of the applied complex FT program – the application of infrared rays (IR), medium-frequency modulated current and kinesitherapy have a proven beneficial effect for increasing the range of movement in the cervical spine. The effects after ICL application are related to skin vasodilatation and hyperemia, reduction of muscle spasm, acceleration of restorative and anti-inflammatory processes, increase of connective tissue elasticity, increase of tissue oxygenation and reduction of local pain. All these changes help to increase the functionality in the cervical region and to increase the range of motion at this level. In the literature, the beneficial effect of the application of III and IV type CMT, in a variable mode, depth of modulations 25% and with a frequency of 100–150 Hz is cited in the treatment of cervical osteochondrosis, with muscle spasm and blockages of the intervertebral joints in the cervical region of the spine pillar. Paravertebral muscle spasm is affected, local blood circulation is enhanced and impaired mobility is restored [25].

In terms of improvement in self-efficacy for activities of daily living as expressed by Cervical Disability Index (NDI) values, there was a decrease in mean values for both groups after completion of physiotherapy – baseline NDI mean values for EG1 and EG2 were identical - 14.2 points (out of 50) and decrease to 9.8 points for EG1 and to 10.4 points for EG2. Three months after the therapy, these values reached for EG1 to 7.7 points and to 7.9 points for EG2 (from 50 points), which is a decrease of 46 pp. for EG1 and 44 p.p. for EG2 compared to baseline levels (from Diagram 6). This indicates the elimination of a significant part of the discomfort in carrying out the daily activities of the studied patients. The effectiveness of the applied therapy for EG1 has a slight advantage over that applied for EG2 immediately after the completion of the FT course – the change in the average NDI values for EG1 patients is -4.400, compared to -3.829 for EG2 patients (from Table 30). But when comparing the changes in the mean values 3 months after the therapy – more significant is the decrease in the mean values for patients from EG2 (-6.314) compared to (-6.250) for EG1 for influencing the activities of daily living represented by the NDI indicator. Further studies are needed on what else patient guidelines should include to increase the effectiveness of applied methods to change daily work and rest habits for patients with chronic neck pain.

An improvement in the psycho-emotional state (PHQ-9) of the studied patients from both groups was reported immediately after completion of the FT course. It is expressed in a decrease in the average values of this indicator – by 2.1 points for EG1 and by 2.2 points for EG2. The reduction of these values three months after physiotherapy is again comparable for both groups - by 1.5 points for EG1 and by 1.7 points from the average values of the PHQ-9 indicator, reached immediately after the end of the FT course (Diagram 5) . The observed tendency to improve the psycho-emotional state and 3 months after therapy correlates with the decrease in pain intensity over time and with the improvement in self-efficacy in daily activities for patients from both groups.

The fourth hypothesis was also confirmed, that the conventional FT, combined with methods to influence the psycho-emotional state of patients from EG2, has a higher effectiveness in the long term, compared to the therapy applied for EG1. Although with a slight advantage, a statistically more significant improvement in the average values of all monitored indicators 3 months after the therapy was observed for the patients from EG2 - the values for Pn₁ & Pn₃, NDI₁ & NDI₃, etc. from Table 30.

Which confirms the hypothesis that the conventional FT program leads to an improvement in the functional state of the subjects, more pronounced in the short term.

In terms of pain, when comparing the change in the mean values for the two groups, the EG2 patients had a slight advantage, both after the completion of the FT course and three months later by following up the pairs #1 (Pn_0 - Pn_1) and #2 (Pn_1 - Pn_3) (Table 30). This advantage is also evident when following the Pearson correlation for this indicator, it is higher for patients from EG2 - for the pairs "before FT - immediately after FT" - for EG2 it is 0.765 and for EG1 - 0.658. Although the achieved reduction in pain intensity as average values was comparable for the two groups of patients, reached immediately after the end of physiotherapy and three months after (Diagram 5).

Regarding cervical mobility, the improvement achieved in different planes was different for the two groups. Follow-up of changes for rotation (by measuring the distance beard - acromion right / left - CAD_R/_L) reported improvement by decreasing mean values after therapy, with a slight difference in the reported results in favor of EG2. For the rotation to the right after completion of the FT course, the average distance for EG1 was achieved – 11.1 cm; compared to 10.7 for EG2. The improvement trend is maintained after 3 months, again with an advantage for patients from EG2: from 10.7 cm for EG1, respectively to 10.2 cm for patients from EG2 for rotation to the right (Diagram 8). Regarding the mobility in the cervical region - for rotation and lateroflexion to the left, we have a minimal advantage of the EG2 patients immediately after the end of the therapy - evident from Diagrams 9,10,11 and through pairs No. 13 (CAD_L_0 – CAD_L_1) and No. 19 (EAD_L_0 – EAD_L_1) – the advantage over the indicators for EG2 is 0.029 cm and 0.457 cm, respectively (Table 30). The advantage of EG2 patients for rotation and lateroflexion to the left is already more significant three months after therapy - when comparing the change in the average values for the two groups through pairs No. 14 (CAD_L_1 – CAD_L_3) and No. 20 (EAD_L_1 – EAD_L_3) (Table 30). For right cervical lateroflexion (by measuring the ear-acromion distance on the right - EAD_R) a higher performance was reported for EG2, both after the completion of the FT course and three months later when comparing the change in mean values with EG1 - through pairs #16(EAD_R_0 – EAD_R_1) and #17(EAD_R_1 – EAD_L_3) (Table 30). Studies that report long-term results for improved mobility mainly follow the effect of monotherapies - using only massage, mobilization or manipulation in the cervical region [33]. Further studies are needed to clarify the difference in effectiveness for influencing mobility in the right and left cervical lobe.

Regarding the impact on the psycho-emotional state of the patients, the majority of EG1 (23 out of 35) and EG2 (22 out of 35) were without symptoms of depression 3 months after the therapy (Diagrams 27 and 31). This shows that the improvement in the functional state is combined with an improvement in the psycho-emotional state. As such, changes for patients in both groups were comparable at 3 months post-therapy, with the difference that baseline PHQ-9 mean scores were higher for EG2 patients. The application of modalities to influence the psycho-emotional state of patients with chronic neck pain could improve the results of applied conventional physical therapy. Additional studies on their application by physical therapists are needed to validate an algorithm to achieve higher long-term effectiveness of the applied therapies.

The effectiveness of the therapy in influencing the clinical symptoms of headache, vertigo and numbness of the upper extremities was also monitored.

Regarding *headache*, the effectiveness of the therapy is higher for EG2 patients. In a significant number of patients - 20 (57.1%) of EG1 and 33 (94.3%) of EG2 had a headache before therapy. Affected

patients with headache 3 months after therapy were 13 for EG1, compared with 17 affected patients for EG2 (Tables 11 and 14). According to McNemar's Test for EG2, headache depended on when it was assessed - it changed both after FT and 3 months after ($p < 0.05$). Physiotherapy is a commonly used adjunctive treatment worldwide for primary or cervicogenic headache (European Federation of Neurological Societies (EFNS) guidelines, Italian primary headache guidelines) [109, 160]. Further research is needed on what are the most effective physiotherapy strategies for its non-pharmacological impact.

Regarding *vertigo* at his EG2 follow-up – it changed immediately after therapy ($p < 0.05$). But this result does not change 3 months later and we can say that the improvement that has occurred is sustainable. We have a higher effectiveness of the therapy for the EG2 patients immediately after the end of the treatment (Table 15). At the vertigo follow-up for EG1 – it did not change immediately after the therapy, but it did change 3 months after the end of the FT course ($p < 0.05$) (Table 12). The conclusion we can make is that the treatments performed affected the complaints of vertigo in the patients of both groups, without proving a higher effectiveness of the EG2 therapy. Cervical vertigo is a common complaint in patients with chronic neck pain, and physical therapy is a good option for treating this vestibular dysfunction. A study by Jaroshevskyi on osteoarthritis in 109 patients showed that a multimodal approach had a maximal therapeutic effect on the elimination of muscle tone disorders, reducing pain syndrome, vertigo and postural instability [90].

When examining *numbness* for EG2 at different time points (before therapy, immediately after therapy, and 3 months after therapy) with the McNemar Test, numbness depends on when it is measured (assessed). It had an effect immediately after the completion of the applied complex physiotherapy for EG2 and the effect was sustained three months later (Table 16). When examining the numbness for EG1 at different times - it does not depend on when it was measured (Table 13). In this case, we can consider that there is no evidence that the numbness was affected by the therapy. The higher effectiveness of therapy for EG2 patients in terms of numbness is probably due to the adjustment of work and rest habits - maintaining good posture, avoiding carrying heavy bags on the shoulder, adjusting the desk and chair so that the computer monitor to be at eye level when sitting, sleeping with an anatomical pillow, relieving stress and anxiety. All these instructions are available in the information leaflet we use. Along with medical treatment, these are the effective recommendations for influencing numbness in cervical radiculopathy according to literature data [110].

In relation **to the fifth hypothesis**, an analysis of the correlation between the subjective variables Pain (Pn), Cervical Disability Index (NDI) and the Patient Health Questionnaire - 9 (PHQ-9) was found different significance for the Pearson correlation coefficient for the tracked pairs of indicators in the different periods.

When tracking the Pearson correlation coefficient for the tracked variables of the same name over time, we can say that a higher correlation coefficient is observed for all indicators of EG2 results. The most significant is the difference in the Pearson coefficient:

- for lateroflexions to the left (EAD_L) – 0.661 for EG1 and 0.943 for EG2;
- for rotations to the left (CAD_L) – 0.751 for EG1, compared to 0.940 for EG2;
- and for NDI – before and after therapy: 0.752 for EG1 versus 0.923 for EG2, evident from Table 32.

A significant correlation was observed between changes in psycho-emotional status and improvement in performance in activities of daily living for patients from both EGs. This is evident by tracing the Pearson correlation coefficient for the PHQ–NDI pair – for EG1 after therapy (0.643), which shows a high dependence 3m after therapy (0.759). For EG2, this coefficient was 0.461 after therapy and increased to 0.564 three months later.

A correlation was also observed between the reduction in pain intensity and the improvement in performance in activities of daily living for patients in both groups, as evidenced by the increase in the Pearson correlation coefficient after therapy and three months later.

The Pearson coefficient for the Pn–NDI pair, for EG1 increased to 0.624, three months after therapy, and for EG2 increased 3 months after therapy to 0.718 (which indicates high dependence) (Chart 42).

The Pearson correlation is weak between the changes in the psycho-emotional state and the intensity of pain, represented by the Pn - PHQ indicators - only 0.337 for the patients from EG1, and 0.313 for the patients from EG2, respectively, three months after the therapy (Tables 41, 43;Diagram 39).

The sixth hypothesis, that after the analysis of the results of the two applied therapies, we can propose optimization of the methods of evaluation and treatment of the patients with chronic pain in the cervical region was confirmed. The application of various methods to influence the psycho-emotional state of patients with chronic neck pain, integrated to the conventional physiotherapy program, improves its effectiveness in the long term. The results of our study give us the basis to formulate several recommendations, one of which is aimed at evaluating and tracking changes in the psycho-emotional state of patients with chronic neck pain. This provides additional guidelines for the selection and preparation of an individual therapeutic program, tailored to the specific changes that have occurred, both on a somatic and psycho-emotional level. Discussion of the disease with the patient, advice on coping with pain and stress, training on the performance of analytical exercises at home, recommendations on the use of ergonomic equipment at work and rest are prerequisites for a better long-term effect of the applied conventional physiotherapy programs. As part of a biopsychosocial approach, they are particularly well-suited to the treatment of chronic musculoskeletal pain, as it is an integrative method that has been proven therapeutically effective in managing the most common symptoms and syndromes in such patients.

5. CONCLUSIONS

1. The assessment and follow-up of risk factors for chronic non-specific neck pain such as overweight, age, gender and injuries improves the selection of a therapeutic program;
2. The use of the questionnaires Cervical Disability Index (NDI) and Psycho-Emotional Status Questionnaire (PHQ-9) are suitable for monitoring the functional and psycho-emotional impact of patients with chronic cervical pain;
3. The timely application of complex physical therapy in patients with chronic herb in the cervical lobe affects their clinical complaints in the short and long term;
4. Optimizing the therapeutic effect in the long term is achieved through the application of complex physical therapy combined with methods to influence their psycho-emotional state;
5. The reduction of anxiety and depression also affects accompanying symptoms such as headache, vertigo and numbness of the upper limbs and contributes to optimal functional recovery;
6. Applied methods of psycho-emotional impact have a stronger impact on women;
7. Updating the diagnostic and therapeutic approach to include and influencing psycho-emotional changes in patients with chronic pain in the cervical region can improve the effectiveness of the therapeutic program for patients with chronic non-specific pain in the cervical region;

6. CONTRIBUTIONS:

6.1. Original scientific contributions

- 1.1. For the first time in Bulgaria, an extended complex assessment of the accompanying psychoemotional changes in patients with chronic neck pain, based on the biopsychosocial model, is offered;
- 1.2. For the first time, a clinical comparative observation of the therapeutic effect was conducted after the application of a conventional physiotherapy program, compared to a physiotherapy program combined with methods of psycho-emotional influence on patients with chronic neck pain.

6.2. Contributions of a confirmatory nature

- 2.1. The application of the Cervical Disability Index (NDI) and the Psycho-Emotional Status Questionnaire (PHQ-9) in patients with cervical pain has been validated;
- 2.2. The therapeutic effectiveness of the application of a conventional rehabilitation program in patients with chronic pain in the cervical region is confirmed in terms of pain intensity, range of motion in the cervical region, efficiency in performing activities of daily living;

2.3. The higher therapeutic effectiveness in the long term is confirmed by the application of a complex rehabilitation program in combination with methods to influence the psycho-emotional state of patients, such as discussing the disease, advice on coping with pain and stress, training in the performance of analytical exercises at home, recommendations for the use of ergonomic equipment at work and rest;

2.4. The existing dependence between the impact on the psycho-emotional state and the efficiency in the performance of the activities of daily living was confirmed for the patients of both groups, both immediately after the therapy and 3 months later.

6.3. Scientific and applied

3.1. An algorithm for the complex assessment of patients with chronic pain in the cervical region is proposed;

3.2. Recommendations are offered to expand the therapeutic approach by using methods to influence the psycho-emotional state of patients with chronic neck pain such as advice on coping with pain and stress, training on the performance of analytical exercises at home, recommendations on the use of ergonomic equipment at work and at rest, together with an information brochure.

3.3 An information brochure for the patient was proposed in order to increase his awareness of the nature of the disease, the prognosis and the possible ways to influence the complaints of patients with chronic neck pain.

7. POSTINGS AND SUBMISSIONS

1. OUR PROPOSAL FOR PHYSIOTHERAPY IN CASES OF CERVICAL OSTEOCHONDROSIS AND SPONDYLOARTHRITIS - D. Gerasimova, I. Takeva, Prevention and Rehabilitation, Year 16, 2022, issue 1-2

2. EFFECTIVENESS OF THE PHYSIOTHERAPEUTIC PROGRAM IN THE TREATMENT OF CHRONIC PAIN IN THE CERVICAL PART OF THE SPINE -
D. Gerasimova, I. Takeva, Physical medicine, rehabilitation, health - issue 3-4, 2022

3. PERSPECTIVES FOR THE APPLICATION OF THE BIOPSYCHOSOCIAL MODEL IN THE TREATMENT OF CHRONIC PAIN IN OSTEOARTHRITIS OF THE SPINE -
D. Gerasimova, I. Takeva, JP News – 08/2023

4. National Congress of Physical and Rehabilitation Medicine
September 22-25, 2022 / Saint Vlas – report on the topic
"EFFECTIVENESS OF THE PHYSIOTHERAPEUTIC PROGRAM IN THE TREATMENT OF CHRONIC PAIN IN THE CERVICAL PART OF THE SPINE" -
D. Gerasimova, I. Takeva, Physical medicine, rehabilitation

5. National Conference "CHALLENGES IN PHYSICAL AND REHABILITATION MEDICINE",
October 13-15, 2023, Plovdiv - report on
"COMPLEX PHYSIOTHERAPEUTIC APPROACH FOR CHRONIC NECK PAIN
IN THE CERVICAL PART OF THE SPINE"- D. Gerasimova, I. Takeva

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